DRAFT

APPENDIX E

HUMAN HEALTH RISK ASSESSMENT METHODOLOGY

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ACRONYMS

AOC	area of concern
BGCR	Background Geochemical Characterization Report
BRA	baseline risk assessment
C	celcius
CDPHE	Colorado Department of Public Health and Environment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CHWA	Colorado Hazardous Waste Act
CLP	contract laboratory program
CNS	central nervous system
COC	chemical of concern
CRAVE	carcinogen risk assessment verification endeavor
CRDL	contract required detection limit
CRQL	contract required quantitation limit
CSF	cancer slope factor
CTS	concentration-toxicity screen
DIL	diluted
DOE	U.S. Department of Energy
DQO	data quality objective
DRCOG	Denver Regional Council of Governments
EATM	exposure assessment technical memorandum
EG&G	EG&G Rocky Flats, Inc.
EPA	U.S. Environmental Protection Agency
ERA	ecological risk assessment
ER	environmental restoration
F	fahrenheit
ft	feet
FWHM	full width half maximum
GC	gas chromatograph
GRRASP	general radiochemistry and routine analytical services protocol
GFAA	graphite furnace atomic absorption
HEAST	Health Effects Assessment Summary Tables
HHRA	human health risk assessment
HI	hazard index
HQ	hazard quotient
IDL	instrument detection limit

IHSS	individual hazardous substance site
in	inches
IRIS	Integrated Risk Information System
kg	kilogram
km	kilometer
L	liter
LHSU	lower hydrostratigraphic unit
m	meter
MDA	minimum detectable activity
MFs	modifying factors
mg	milligram
mi	mile
MLE	maximum likelihood estimator
MS	mass spectrometry
MSA	method of standard addition
μg	microgram
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
OU	operable unit
pCi	picocurie
PCOC	potential chemical of concern
PGR	preliminary remediation goals
PPRG	programmatic preliminary remediation goal
QAPjP	Quality Assurance Project Plan
QC	quality control
rad	radionuclide
RAGS	Risk Assessment Guidance for Superfund
RBC	risk-based concentration
RCRA	Resource Conservation and Recovery Act
RFCA	Rocky Flats Cleanup Agreement
RfCs	reference concentrations
RfD	reference dose
RFEDS	Rocky Flats environmental database system
RFETS	Rocky Flats Environmental Technology Site
RFI/CMS	RCRA Facility Investigation/Corrective Measures Study
RI/FS	Remedial Investigation/Feasibility Study
RFLII	Rocky Flats Local Impacts Initiative

RI/RFI	Remedial Investigation/RCRA Facility Investigation
RME	reasonable maximum exposure
SOP	standard operating procedure
SPARCC	sensitivity, precision, accuracy, representativeness, completeness, and comparability
SQL	sample quantitation limits
SVOC	semivolatile organic compound
TDS	total dissolved solids
TIC	tentatively identified compound
TM	technical memorandum
TOC	total organic carbon
UBDS	uniform baseline data set
UCL	upper confidence level
UHSU	upper hydrostratigraphic unit
UTL	upper tolerance limit
VOC	volatile organic compound

DEFINITIONS

Applicable or Relevant and Appropriate Requirements. "Applicable" requirements are those cleanup standards, standards of control, and other substantive environmental protection requirements, criteria, or limitations promulgated under federal or state law that specifically address a hazardous substance, pollutant, contaminant, remedial action, location, or other circumstance at a CERCLA site. "Relevant and appropriate" requirements are those clean-up standards which, while not "applicable" at a CERCLA site, address problems or situations sufficiently similar to those encountered at the CERCLA site that their use is well-suited to the particular site. ARARs can be action-specific, location-specific, or chemical-specific.

Area of Concern. One or more source areas grouped spatially in close proximity and considered as one area for the purpose of data aggregation and exposure area determination within the Baseline Risk Assessment.

Baseline Risk Assessment. An analysis of the estimated potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action).

Cancer Risk. Incremental probability of an individual developing cancer over a lifetime as a result of exposure to a potential carcinogen.

Cancer Slope Factor. A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The cancer slope factor is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.

CERCLA Baseline Risk Assessment. (Human Health Evaluation) Under sections 104 and 121 of CERCLA, the U.S. Environmental Protection Agency is required to assess the risks to human health posed by uncontrolled hazardous waste sites on the National Priority List. That assessment is conducted in the remedial investigation/feasibility study phase of the site cleanup process. When applied to the evaluation of the human health impacts caused by uncontrolled CERCLA sites (i.e., if no remedial action is taken), this process is termed the "baseline risk assessment."

Chemical of Concern. Any element, chemical, or radionuclide of anthropogenic origin present in sufficient concentration to warrant risk assessment for potential remediation, and where data quality is sufficient for risk assessment.

Comprehensive Risk Assessment for the RFETS. A site-wide iterative, increasingly quantitative analysis of the risks posed by historical and current activities to worker health, public health, ecological receptors and processes, and to natural resource services.

Conceptual Site Model. A "model" of a site developed at scoping using readily available information. Used to identify all potential or suspected sources of contamination, types and

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concentrations of contaminants detected at the site, potentially contaminated media, and potential exposure pathways, including receptors. This model evolves as more and additional is gathered and is also known as "conceptual evaluation model."

Conservative Screen. The CDPHE process where the application of risk-based concentrations to specific IHSS or source areas to determine whether the area is a candidate for No Further Action, for inclusion in a Baseline Risk Assessment, or for Voluntary Cleanup Action.

Corrective Measures Study. The portion of a RCRA corrective action that is generally equivalent to a feasibility study conducted under Superfund.

Data Quality Objectives. Qualitative and quantitative statements that are developed before sampling begins to identify the quality of data that must be collected before CERCLA actions.

Data Validation. Evaluation, against defined criteria, of the technical aspects of sampling, handling, field measurements, and lab analysis for problems that could affect the validity or usability of the analytical result.

Detection Limit. The lowest amount that can be distinguished from the normal "noise" of an analytical instrument or method.

Ecological Risk Analysis. The determination of the probability and magnitude of adverse effects of environmental hazards on nonhuman biota, also called an Ecological Risk Assessment or Environmental Risk Analysis.

Exposure Area. The area in which a potential receptor can reasonably be expected to contact COCs over a specified exposure duration. An exposure area can vary in size, depending on site-specific conditions and potential receptors. Default exposure areas for RFETS are 50 acres for ecological researcher or recreational user, 30 acres for commercial/industrial workers, and 10 acres for residential receptors.

Exposure Assessment. The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure Pathway. The course a chemical or physical agent takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals or physical agents at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure medium (e.g., air) or media (in cases of intermedia transfer) also is included.

Exposure Point. A location of potential contact between an organism and a chemical or physical agent.

Exposure Route. The way a chemical or physical agent comes into contact with an organism (i.e., by ingestion, inhalation, dermal contact).

Feasibility Study. A study undertaken by the lead agency to develop and evaluate options for remedial action. The FS emphasizes data analysis and is generally performed concurrently and in an interactive fashion with the remedial investigation, using data gathered during the RI. The RI data are used to define the objectives of the response action, to develop remedial action alternatives, and to undertake an initial screening and detailed analysis of the alternatives. The term also refers to a report that describes the results of the study.

Hazard Quotient. The ratio of a single substance exposure level over a specified time period (e.g., chronic) to a reference dose for that substance derived from a similar exposure period.

Hazard Index. The sum of hazard quotients for multiple substances and/or multiple exposure pathways. The HI is calculated separately for chronic, subchronic, and shorter-duration exposures.

Individual Hazardous Substances Site. An individual location where hazardous substances have come to be located at a discrete area within the larger "Site."

Interagency Agreement. A formal, negotiated agreement among EPA Region VIII, the State of Colorado, and the RFFO on the technical aspects and milestones for the cleanup of the RFETS.

No Further Action. A designation, approved by EPA/CDPHE, that an IHSS, OU or source area has been assessed and that the estimated risks to humans and environment have been determined to be negligible. Therefore, no remedial action is required.

Potential Chemicals of Concern. Chemicals that are potentially site-related and whose data are of sufficient quality for use in the quantitative risk assessment.

Preliminary Remedial Goals. Initial clean-up goals that (1) are protective of human health and the environment and (2) comply with ARARs. They are developed early in the process based on readily available information and are modified to reflect results of the baseline risk assessment. They are also used during analysis of remedial alternatives in the RI/FS.

Quality Assurance Project Plan. Describes the policies, organization, functional activities, and quality assurance and quality control protocols necessary to achieve DQOs dictated by the intended use of the data.

Reasonable Maximum Exposure. The highest exposure that is reasonably expected to occur at a site.

Reference Dose. A preferred toxicity value for evaluating noncarcinogenic effects resulting from exposures at Superfund sites. It is an exposure level for the human population, including

sensitive subpopulations, that is likely to be without an appreciable risk of adverse effects over the period of interest.

Risk Assessment. An evaluation of the potential adverse impact of a given event (e.g., an accident or the release of a hazardous substance) upon the well-being of a person or a population of humans or biota. It is a process by which information or experience concerning the cause and effect under a set of circumstances (e.g., exposure) is integrated with the extent of those circumstances to quantify or otherwise describe risk.

Risk Management. The process of deciding what actions to take in response to an estimated risk.

Risk-Based Concentrations. Concentration levels for individual chemicals that correspond to a specific cancer risk level (e.g., 10^{-6}, 10^{-4}) or hazard quotient (e.g., less than or equal to 1). They are generally selected as preliminary or final remediation goals when ARARs are not available.

Source Area. Areas containing organic PCOCs above reporting limits and/or inorganic PCOCs at concentrations or activities above the arithmetic mean plus two standard deviations on the background data.

Toxicity Assessment. The toxicity assessment is an evaluation of the type of adverse health effects associated with exposure to the chemicals of concern and the magnitude of that exposure. The evaluation typically considers uncertainty, which is a statement that describes the confidence of the supporting information used for the toxicity evaluation.

Uncertainty Analysis in CERCLA Risk Assessment. The evaluation of the unknowns associated with qualitative and quantitative risk analysis introduced by: (1) lack of representativeness in sampling of environmental media analyzed and the heterogeneity of physico-chemical characteristics of those media; (2) analytical errors and matrix interferences; (3) unknowns in exposure scenarios; (4) inadequacies of toxicity effects and the concentrations at which those occur resulting in a lack of approved toxicity criteria; (5) inadequate characterization of routes of exposure, transport processes; and (6) inadequate understanding of synergistic effects on receptors of multiple contaminants.

1.0 INTRODUCTION

This document prescribes the methodology for conducting the Human Health Risk Assessment (HHRA) portion of Baseline Risk Assessment (BRA) for the Rocky Flats Environmental Technology Site (RFETS). The HHRA, coupled with the Ecological Risk Assessment (ERA), comprises a BRA. In accordance with the requirements of the Rocky Flats Cleanup Agreement (RFCA) among the U.S. Department of Energy (DOE), U.S. Environmental Protection Agency (EPA), and the State of Colorado, BRAs are performed for each of the Operable Units (OUs) defined in the agreement.

1.1 Purpose

The purpose of this HHRA methodology is to direct risk assessors for RFETS to relevant documents and site-specific agency agreements to produce HHRAs that are acceptable to both the EPA, DOE, and the State of Colorado. The State of Colorado is represented by the Colorado Department of Public Health and Environment (CDPHE). To achieve this purpose, it is necessary to understand the purpose of an HHRA.

The purpose of the HHRA is to develop a quantitative description and assessment of the risk to the public posed by the chemicals of concern (COCs) at an OU. Specifically, goals of the HHRA include providing:

- An analysis of baseline human health risks to help determine the need for action at sites
- A basis for determining levels of contaminants that can remain onsite and still be adequately protective of public health
- A basis for comparing potential health impacts of various remedial alternatives
- A consistent process for evaluating and documenting risks to public health
- Information for effective risk management.

1.2 Scope

The scope of this document is to summarize key sections of existing agency guidance, and integrate RFETS-specific documents and agency agreements with published agency guidance. Current EPA guidance for risk assessment, Risk Assessment Guidance for Superfund (RAGS) (EPA, 1989a), encompasses the full spectrum of situations that may be encountered at Superfund sites. As a result, it is written in general terms. This HHRA methodology reviews some of the key sections that directly apply to RFETS, and refers the reader to RAGS for additional background.

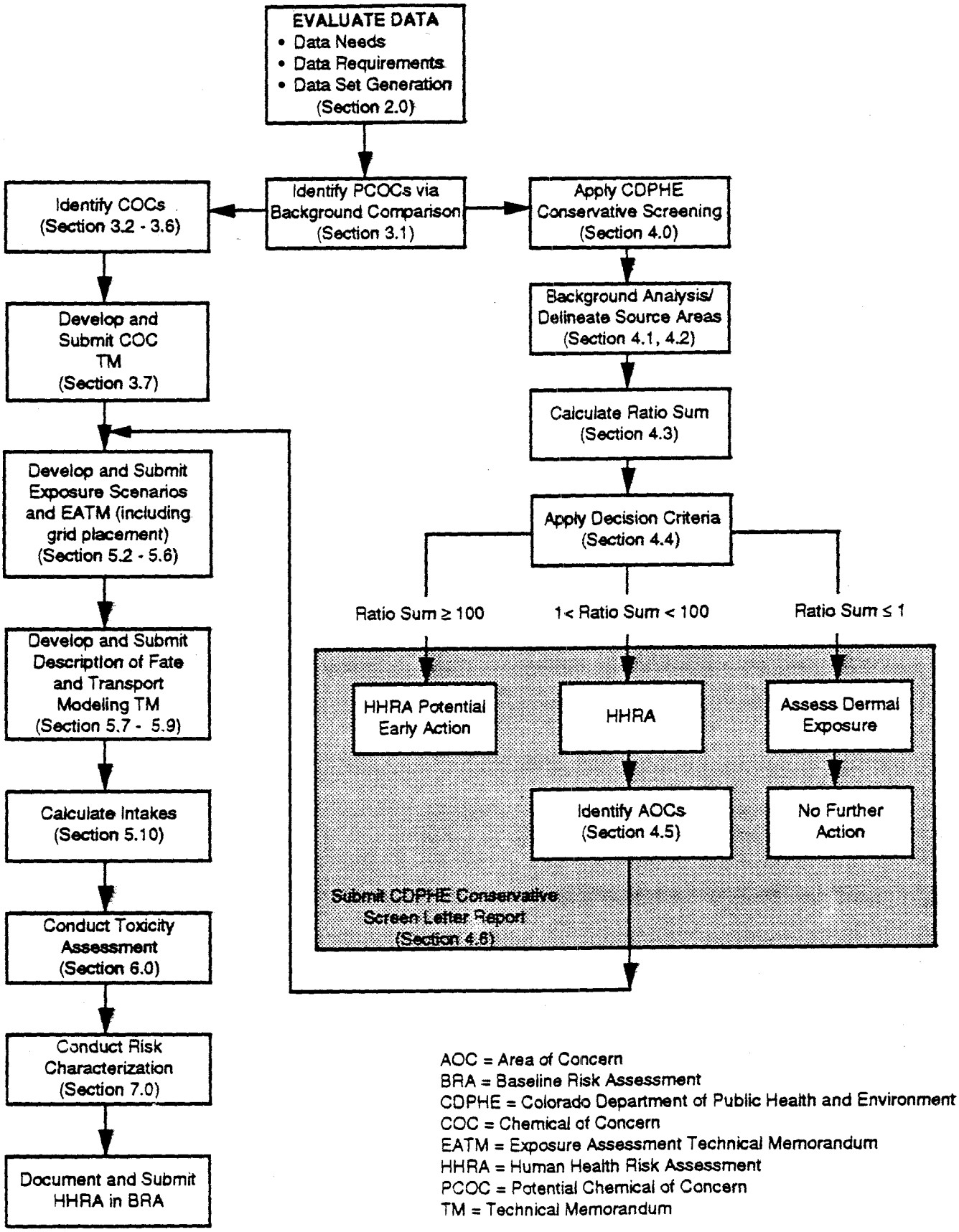
The RFETS specific risk assessment policy as defined by the DOE Rocky Flats Field Office (RFFO) is documented in RFI 5480.3, Rocky Flats Field Office Risk Assessment Policy, (DOE 1994a). This policy defines the roles and responsibilities of the RFFO and its contractors for meeting applicable requirements when conducting risk assessments at the RFETS, (DOE 1994a). The RFFO policy should be consulted for additional RFETS specific information and references.

Several risk assessment topics have been the subject of discussion and agreement among DOE, EPA, and CDPHE. Where appropriate, this document references or summarizes existing DOE, EPA, and CDPHE documents or agreements. Figure 1-1 illustrates the RFETS HHRA methodology specified in the DOE, EPA, and CDPHE agreements. References to relevant sections of this document are also provided. Supporting materials for conducting specific steps of the risk assessment process have been developed at RFETS and are referenced or summarized in this methodology. In addition, example text or table shells are provided to guide the risk assessor in documenting the HHRA. Risk assessors for each OU must ensure that the content of the HHRA satisfies the OU-specific objectives.

1.3 Rocky Flats Environmental Technology Site Information

General information about RFETS that is relevant to an HHRA includes the site history, the regulatory framework, and a physical description of the site. Site history and regulatory framework is found in the RFETS cleanup workplan, (CWP), (CWP, 1995) Section 1.0

Figure 1-1 HHRA METHODOLOGY



AOC = Area of Concern
BRA = Baseline Risk Assessment
CDPHE = Colorado Department of Public Health and Environment
COC = Chemical of Concern
EATM = Exposure Assessment Technical Memorandum
HHRA = Human Health Risk Assessment
PCOC = Potential Chemical of Concern
TM = Technical Memorandum

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Introduction. RFETS site physical description is provided in the CWP, (CWP, 1995) Section 2.0, Site Description. OU-specific information may be found in detail in the individual OU workplans, the CWP, and the first few sections of the Remedial Investigation/Resource Conservation and Recovery Act (RCRA) Facility Investigation (RI/RFI) report. This information may be summarized from the RI/RFI report and included in the HHRA to allow it to be a "stand alone" document. References can direct the reader to the source document for further detail.

The Uniform Baseline Data Set (UBDS) should also be consulted (when it becomes available) for RFETS specific information. Examples of information that will be available from the UBDS are RFETS demographics and exposure parameters. The UBDS is being developed in 1994 and 1995 and its use will be required in fiscal year 1996.

1.4 HHRA Methodology Organization

This document is organized into the following sections, which together represent the components of the DOE, EPA, and CDPHE agreements integrated with the traditional CERCLA/RCRA HHRA methodology:

- Data Evaluation
- Identification of COCs
- CDPHE Conservative Screen of PCOCs
- Exposure Assessment
- Toxicity Assessment
- Risk Characterization
- HHRA Report.

2.0 DATA EVALUATION

The first step in conducting an HHRA at RFETS is data evaluation. Components of data evaluation include identification of data needs and data requirements prior to data collection and the subsequent generation of a usable data set for the HHRA. These components are discussed in the following subsections.

2.1 Data Needs Identification

Identifying data needs, specifically for the HHRA, is one component of overall RI/FS planning. The definition of HHRA data needs is integrated with the definition of data quality objectives (DQOs) for the RI/FS. Data for each of the major components of the HHRA are needed to adequately assess the current and future risk posed by a site. However, because the data input to site characterization and to the exposure assessment are site specific (i.e., are unique to the contaminants and physical characteristics of a site), emphasis during the planning stages is on these components. Data needs associated with the toxicity assessment and risk characterization are assessed after the site characterization is complete and in parallel with the exposure assessment. Data for the toxicity assessment typically consist of EPA-derived toxicity values and uncertainty factors.

This section discusses the data needs relevant to the components of the HHRA process. Additional instruction is provided in *Guidance for Data Useability in Risk Assessment, (Parts A and B)*, (EPA, 1992a) and RAGS, (EPA, 1989a), as well as:

- *Guidance for Planning for Data Collection in Support of Environmental Decision-Making Using the Data Quality Objectives Process*, (EPA, 1994a)
- *Draft RFETS Data Management Plan for ER Management* (EG&G, 1994a)
- *Rocky Flats Plant Site-Wide Quality Assurance Project Plan for CERCLA RI/FS and RCRA RFI/CMS Activities* (EG&G, 1991).

Data needs for site characterization, exposure assessment, toxicity assessment, and risk characterization are discussed in the following subsections.

2.1.1 Site Characterization Data

Data collected to support site characterization are used in the RI/FS/Remedial Design/Remedial Action process; thus, the development of HHRA data requirements parallels the data requirements to meet the DQOs. For HHRA purposes, the output of the site characterization is measured or modeled concentrations of contaminants in each of the source areas (i.e., IHSSs) and medium of concern. Data needs are formulated in terms of characterizing the source-pathway-receptor. Generally data used for the HHRA include characterization of:

- The source or sources of contamination
- The extent of contamination in each medium potentially affected
- The potentially affected media with which a current or future receptor may come in contact.

Depending on the detail of source characterization data available in historical information (e.g., disposal records, previous investigations, removal records), the source characteristics may be well known or interpolated. The *Historical Release Report* (DOE, 1992) documents an extensive effort to gather information at the IHSS level for use in determining the potential source characteristics. The need for additional source characterization is determined during project scoping and, if additional characterization is conducted, should include an analyte suite which encompasses the list of chemicals of potential concern and transformation products for those chemicals.

As discussed in Sections 4.0 and 5.0, the contaminant concentration distributions will be used to delineate source areas and areas of concern at the OU level. Characterization of the extent of contamination encompasses contaminant concentration distributions within the IHSSs and those contaminants that have potentially migrated outside of the IHSSs. Fate and transport

modeling can be used to predict concentrations that may effect future receptors. For the RI as well as the HHRA, all media presenting a potential exposure route or transport mechanism should be characterized for the chemicals suspected in the source. This characterization allows the development of the conceptual site model. The number and locations of samples included in the HHRA should allow for characterization of:

- Statistical comparison with background concentrations for each medium of concern
- Statistical distributions of contaminant concentrations for each medium of concern
- Contaminant levels that can be compared to risk-based concentrations
- All potential exposure points within each medium
- Migration to potential exposure points including input data for fate and transport models
- Potential exposures based on possible future land uses.

2.1.2 Exposure Assessment Data

The exposure assessment uses the site characterization data to estimate exposure-point concentrations for each medium of concern and area of concern. Via conceptual model development and fate and transport modeling, exposure-point estimates can be calculated for future receptors. Data needs for the exposure assessment are summarized as follows:

- Contaminant release rates from the source (either known or modeled)
- Physical, chemical, and biological parameters for evaluating transport and transformation of site-related chemicals
- Parameters to characterize receptors according to their activity, behavior, and sensitivity
- Estimates of exposure concentrations for COCs, environmental media, and receptors at risk
- Estimates of chemical intake or dose for receptors via all exposure pathways and in exposure areas.

2.1.3 Toxicity Assessment Data

As indicated in Section 2.1, the data for toxicity assessment typically consists of EPA-derived information regarding the potential for particular contaminants to cause adverse health effects. In a toxicity assessment, data are collected from acceptable sources of information. Toxicity assessments are procedural and include the following steps:

1. Gather qualitative and quantitative toxicity information for COCs
2. Determine toxicity values for noncarcinogenic effects
3. Determine toxicity values for carcinogenic risks
4. Summarize the toxicity information.

Data required for the toxicity assessment include:

- All available toxicity values for all chemicals and exposure pathways
- Uncertainty factors and confidence measures for reference doses (RfDs) and weight-of-evidence classifications for cancer slope factors (CSFs).

2.1.4 Risk Characterization Data

The risk characterization is an integral component of the HHRA that combines the output of the exposure assessment and toxicity assessment to interpret, present, and quantify the results of the HHRA. Because of this output, specific data needs for risk characterization are similar to data needs previously identified.

2.2 Data Quality Objectives Development

The development of DQOs identifies the data requirements for the HHRA. Establishing the DQOs is discussed further in the RFETS CWP, (CWP, 1995), Section 4.4.5 Data Quality Objectives.

2.3 Data Set Generation

Data sets generated from RFEDS output require "cleanup" and treatment prior to use in the HHRA. The data-set-generation steps are described in the following sections.

2.3.1 Data Cleanup

The "data cleanup" of RFEDS output is a task to make the data consistent. The process as provided in a memorandum from M. Siders regarding "Practical Suggestions for Users of RFEDS Data" (EG&G 1994b) and detailed in Appendix A, consists of a series of steps which includes:

- Standardization of units
- Standardization of geologic codes
- Standardization of locations if the location designation has changed over time
- Standardization of analyte names (usage has changed over the years)
- Deletion of blank "form-generated" records for which no results are given
- Exclusion of QC data from the working data set
- Removal of any rejected data (Validation code = "R")
- Replacement of non-validated records with corresponding validated records (if available)
- Correction of incorrect units (e.g., pH should have "PH" as the unit, *not* "MG/L" as the unit)
- Treatment of DUP/REAL pairs
- Appropriate use of diluted (DIL) results
- Outlier analysis.

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2.3.2 Data Treatment

The manner in which analytical results are classified as non-detects is dependent upon the analyte group. The following discusses non-detect classification for radionuclides, organic, and inorganic analytes as summarized from M. Siders memorandum dated April 5, 1994 (EG&G 1994b).

- All data for radionuclides should be used as detects, except for rejected data (Validation code = R). For radionuclide data, DOE Order 5400 states, "All of the actual values, including those that are negative, should be included in the statistical analyses."

- For organics, the result qualifier (entered in the Qualifier field) should be used to determine the percentage of non-detects. Non-detects for organic analytes are generally qualified "U", but other designations may also appear in the result-qualifier field.

  Positive detections (i.e., "hits") of some common laboratory contaminants such as acetone, methylene chloride, and certain phthlates may indicate cross-contamination if detected in the associated laboratory blank; such sample results are designated as a "B" in the Qualifier field. EPA guidance for data validation and risk assessment (EPA, 1989a) indicates that if the concentration of a common lab contaminant in a sample is more than 10 times the concentration of the sample analyte in the associated blank, then the sample result is taken to be real (i.e., a "hit"), not attributable to laboratory contamination. For other analytes that are not typically found as laboratory contaminants, EPA guidance (EPA, 1989a) states that if the concentration in the sample exceeds five times the concentration in the associated blank, then the sample result is taken to be real, not attributable to laboratory contamination.

- For metals and other chemical parameters (inorganics), it may be ineffective to rely on the result qualifier alone. The following criteria have been employed to differentiate detects from non-detects, and are suggested as guidelines for the data:

  — If the Qualifier field contains a "U", the result is used as a non-detect (i.e., censored data point).

  — If the Qualifier field is blank and the result is greater than the reported detection limit, the result is used as a detected value, barring evidence to the contrary.

  — If the Qualifier field (for inorganics) contains a "B", which indicates that the result was above the IDL but below the CRDL, the result is used as a detected value.

  — Other characters may also be found in the Qualifier field, and, barring any other evidence to the contrary, these are generally accepted as detects.

Data-treatment requirements with respect to HHRA COC identification and calculation of exposure-point concentrations includes replacement of non-detect values. With the exception of the Gehan Test (used as part of the background comparison), non-detect values should be replaced with 0.5 times the reported detection limit in accordance with Section 5.3.3 of RAGS (EPA, 1989a).

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3.0 IDENTIFICATION OF CHEMICALS OF CONCERN

This section describes the methodology used to identify COCs for which potential risks for each RFETS OU will be estimated. The goal of selecting COCs in this phase of the HHRA is to identify specific chemicals in each environmental medium that may pose human health hazards. Once identified, COCs will be advanced through the quantitative risk assessment to characterize risk for all current and potential future human receptors.

The first step of COC selection involves identifying PCOCs which includes distinguishing sample data from background data. Following this, the selection of COCs for the HHRA proceeds simultaneously with the CDPHE Conservative Screen (described in Section 4.0). The relationship between the CDPHE Conservative Screen and the HHRA process is illustrated in Figure 1-1.

The following screening criteria will be applied to all chemicals detected in each environmental medium (surface soil, subsurface soil, surface water, groundwater, sediments, and air) to select COCs for each OU:

- Background comparison for inorganic chemicals (including radionuclides)/ PCOCs
- Human essential-nutrient analysis
- Frequency of detection analysis
- Risk-based concentration screen
- Concentration-toxicity screen
- Professional judgement.

Figure 3-1 presents the flowchart for applying the screening criteria. Elimination criteria will be applied in the order presented; at each decision point, the chemical will be eliminated

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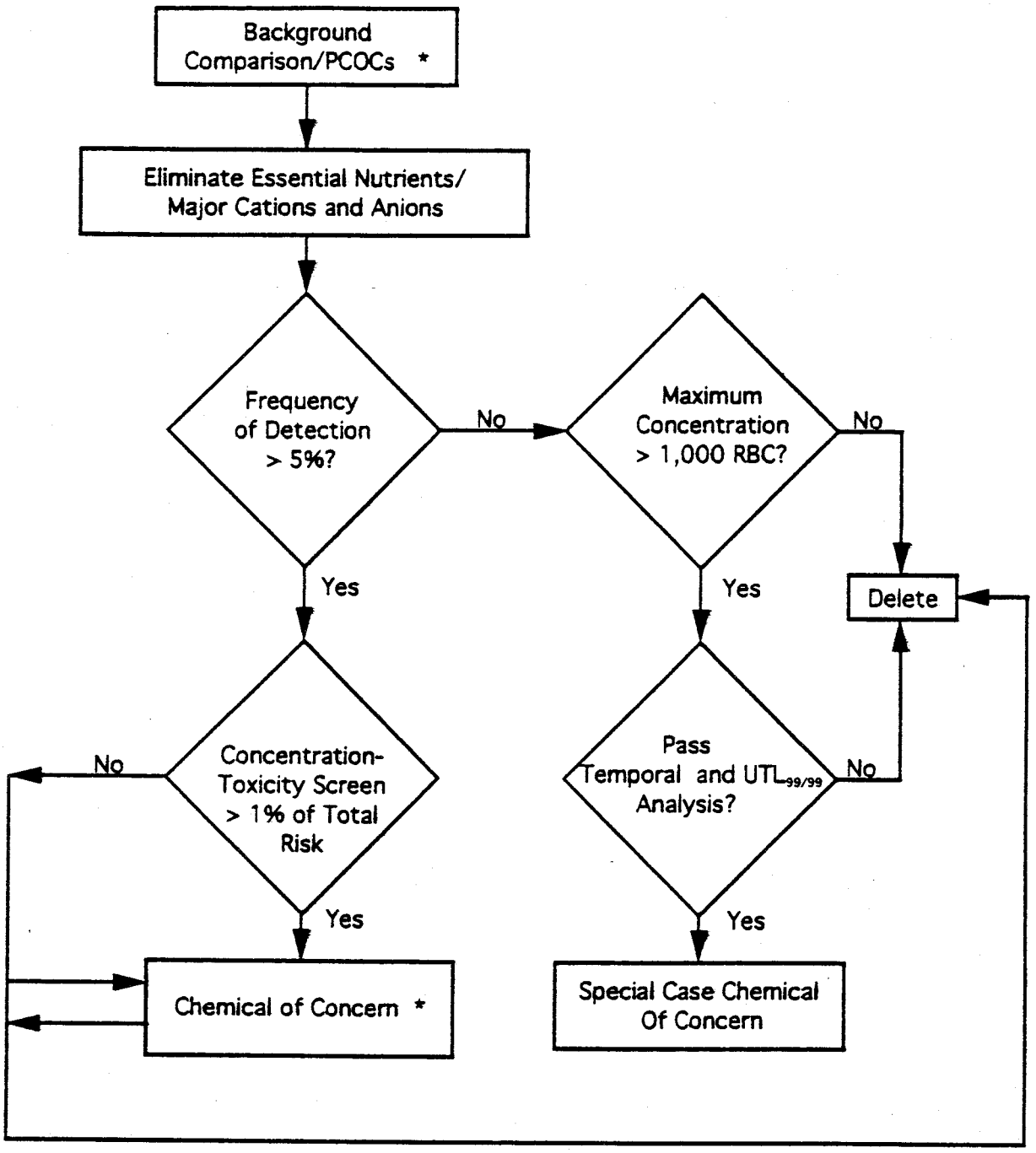
Figure 3-1 COC Identification



* Professional Judgement Applied to These Analytes

or retained for further consideration. Prior to initiation of the screening process, data will be aggregated by medium and analyte. A summary presentation of the data is discussed further in Section 3.7 and will include:

- Chemical name
- Chemical-specific contract required quantitation limit (CRQL)
- Reported detection limit
- Frequency of detection
- Minimum detected concentration
- Maximum detected concentration
- Arithmetic or geometric mean concentration.

3.1 Background Analysis

The first step in the COC selection process is to distinguish between contamination associated with site activities and nonanthropogenic (naturally occurring) background conditions. To make this determination, a background analysis is conducted. Professional judgement must be applied to ensure the background data set is appropriate for comparison to the OU data set, (for example geologic conditions should be considered). The output of the background analysis is a list of PCOCs. Figure 3-2 illustrates the PCOC identification process.

The statistical methodology used to conduct the background analysis (i.e., PCOC identification) for nonanthropogenic compounds has been developed and approved by DOE, EPA, and CDPHE. Additional clarification was provided through the EG&G Rocky Flats ER Management (EG&G, 1995).

Methods used to analyze whether a metal or radionuclide exceeds background levels include a five-phase process methodology, with the final phase of PCOC selection to be application of "professional judgement." The reader is referred to Gilbert (1993) for the full explanation. Appendix B, Background Comparison for Metals and Radionuclides, contains additional information and summarized guidance. The fourth phase consists of a battery of statistical tests as summarized in the following bullets.

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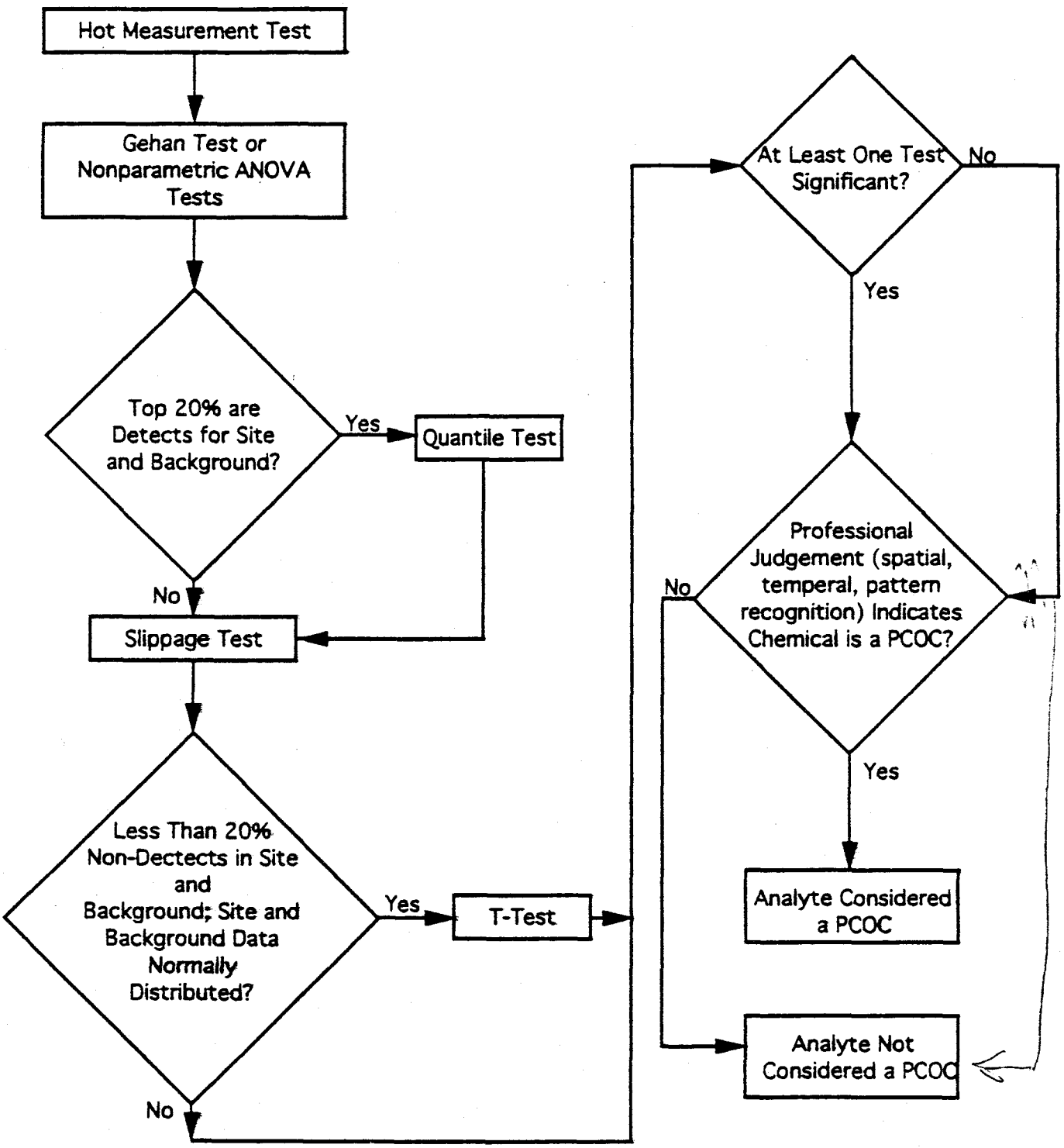
Figure 3-2 PCOC Identification



- Analytical results for metals, radionuclides, and water-quality parameters are compared to the background data using up to four statistical tests: the Quantile test, Slippage test, Student's t-test, and the Gehan test as described in a letter report by Gilbert (Gilbert, 1993). The analyte is considered to be above background if it fails any test at the $p \leq 0.05$ significance level, provided the test is supported by an appropriate data set. Analytes with greater than 80% cannot be compared using statistical tests, and test results for analytes having 50 - 80% nondetects should be reviewed with caution.

- Lognormal upper tolerance level ($UTL_{99/99}$) comparison is performed. The background $UTL_{99/99}$ presented in the Background Geochemical Characterization Report (BGCR) (EG&G, 1993) are calculated assuming that the background data are normally distributed, (probability plots or Shapiro-Wilks tests may be used). This assumption may not be appropriate for all analytes. An updated set of tables, produced using current data-treatment protocol (EG&G 1994b) includes UTL calculations for both normal and lognormal distributions (EG&G, 1994c; EG&G, 1994d). Concentrations of some analytes may be within the background range according to all statistical tests performed, but one or two results may exceed the background $UTL_{99/99}$. This results in identifying the analyte as a potential chemical of concern. When the distribution of the background data is tested, if the better fit is a lognormal distribution, the $UTL_{99/99}$ will be recalculated based on lognormal distribution and the site results will be compared to the lognormal-based $UTL_{99/99}$. This statistical re-evaluation may result in excluding some analytes as PCOCs. Again, UTLs cannot be reliably calculated for analytes with a very high rate ($>80\%$) of nondetects, so always check the percentage of nondetects for all analytes listed in the tables.

The source of background data is the *Background Geochemical Characterization Report* (BGCR) (EG&G, 1993) but revised tables of summary statistics and UTLs have been produced using the data from the 1993 BGCR (EG&G 1994c; EG&G 1994d). These more recent tables supply the results of distributional testing (Shapiro-Wilk) and both normal and lognormal UTL values. Use of these more recent tables is required. Because samples of surficial soils were not collected and analyzed for the original BGCR program, OUs 1 and 2 collected samples of surficial soil from the Rock Creek background area. To date, these data were the only validated background data for surficial soils. However, as a second phase of the BGCR, a study of background surficial soils was initiated in 1994.

If the battery of statistical tests indicates a statistical difference above background levels, the chemical will not be eliminated under phase 4 of the comparison methodology. An exception

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to this rule will apply if the statistical tests are inappropriate for the data set. For example, if a Student's t-test is initially used because it is assumed that the underlying probability density function is Gaussian, but further analysis reveals this assumption to be unsubstantiated, the result from the statistical test would be invalidated. As indicated on Figure 3-2, professional judgement will be used to retain or eliminate chemicals depending on the appropriateness of the statistical test. Professional statisticians should be consulted prior to eliminating such contaminants. Presentation of the results of the background comparison will include descriptive statistics, statistical tests, power of tests, and results of the test.

3.1.1 Background Analysis Professional Judgement

An EG&G interoffice memo adequately describes the professional judgement section of background analysis (EG&G, 1995). This memo is summarized in this section.

> As described below, professional judgement is narrowly defined. It can be used to include a chemical that did not appear to be significantly different from background based on the results of the statistical tests, but which the OU manager believes should be included because of a preponderance of historical data suggesting that the chemical may have been released in significant quantities to the environment. Professional judgement can also be applied to exclude a chemical for which at least one of the statistical tests was significant, but the difference from background can be explained by spatial, temporal, or pattern-recognition concepts.
>
> Professional judgement may also determine that there was an invalid application of the statistical tests (e.g., distributional assumptions were violated; non-detect rates were so high that the statistical tests actually compared replacement (i.e., "fabricated" values; etc), thereby making the test results highly suspect or meaningless. The reader is referred to Gilbert (1987) or other statistical texts for a detailed discussion. However, Gilbert has stated that the analyst should "...not compute the Wilcoxon Rank Sum test if more than 40% of either the reference-area or cleanup unit measurements are less-than values" and that "if fewer than r measurements are greater than the limit of detection, then the Quantile test cannot be performed" (Gilbert and Simpson, 1992). The value of r must be determined from tables (see Gilbert and Simpson, 1992).
>
> The Environmental Protection Agency (EPA) and the Colorado Department of Public Health and the Environment (CDPHE) have agreed that phase five of professional judgement shall be limited to an analysis of (1) spatial, (2) temporal, and (3) pattern-recognition concepts.

1. Spatial analysis requires concentrations of each PCOC to be plotted on a map; assessment of the plotted data should indicate the presence (or absence) of any trends in concentration, and assist in delimiting any "hot spots."

2. Temporal analysis is particularly relevant for groundwater data, where repeated sampling at one well offers the opportunity to evaluate changes in analyte concentrations over time. Time-series plots are used for this evaluation. Temporal analysis of data for sediment or other geologic materials is less useful or may not even be applicable.

3. Pattern recognition includes such aspects as inter-element correlations (as noted by Gilbert, above), similarities in geochemical behavior, geochemical modeling to determine solubility controls on element concentrations, correlation between elemental concentrations and certain parameters (total suspended solids (TSS); the negative logarithm of the hydrogen ion activity (pH); reduction-oxidation potential (Eh or pe, where Eh=0.059*pe); clay content; organic content; cation-exchange capacity; etc.), and other recognizable patterns in elemental behavior. Comparison between TSS (continued) and "total" metals or "total" radionuclides should indicate if the analyte resides in the solid (particulates or sediments) or aqueous phase (i.e., in solution); note, however, that the human health risk is based on the unfiltered samples so the chemical cannot be excluded as a PCOC based on a good correlation with TSS. Redox-sensitive species (sulfur, iron, vanadium, arsenic, antimony, selenium, uranium, manganese, etc.) have mobilities related to Eh, in addition to pH and composition. A geochemist should be consulted to evaluate these, and other, patterns of element behavior.

However, with regard to TSS correlations, if the data analyst can show that TSS values in the OU sample markedly exceed those of background, this may be grounds for eliminating a metal or radionuclide. TSS correlations must be carefully evaluated on a case-by-case basis.

In addition to these forms of professional judgement, the validity of the application of statistical tests should also be evaluated. For example, statistical comparison of data sets where one or both data sets have high non-detect rates or high value non-detects may well be an invalid use of the statistical tests (see Gilbert and Simpson, 1992). As noted by Helsel (1990) "...the fabrication of data followed by a t-test must be considered too arbitrary for use especially for legal or management decision purposes, and should be avoided." The 'fabrication of data' here is the same as "replacement of non-detect data" (i.e., replacement with a value such as half the detection limit, or a value generated by maximum likelihood estimation calculations). Helsel (1990) defines a "small" amount of censoring as less than 20 percent non-detects, a "moderate" amount of censoring as 20 to 50 percent non-detects, and a "large" amount of censoring as greater than 50 percent non-detects. (NOTE: "censored" is used here in the statistical sense, as indicating those data that are below the analytical detection limit. These data are used by replacement with a proxy value, such as one half of the detection limit, or given a ranking in nonparametric

tests). For EG&G Rocky Flats, various reports (DOE, 1993a; DOE, 1994b; and others) have used 80 percent as the cut-off value for non-detects. However, all data analysts should realize the inherent uncertainty of statistical test results that are produced using data sets with greater than 50 percent non-detects.

In addition to high non-detect rates invalidating the results of statistical tests, other potential pitfalls in the application of statistical tests include violation of distributional assumptions, variance assumptions, data independence assumptions, etc. For example, if parametric tests are used, the data sets should be normally distributed and have approximately equal variances. If such assumptions are grossly violated, the results of such statistical tests are certainly suspect. For a more in-depth discussion of statistical tests, the reader is referred to Gilbert's letter report (1993), or to the many statistical texts that describe the assumptions of various statistical tests and the validity of their application.

In summary, professional judgement is applied on a case-by-case basis. Also, DOE has agreed to bear the "burden of proof" in all applications of professional judgement. All such judgement must be backed up by thorough and thoughtful analysis of the available evidence. Maps, figures, and references supporting the professional judgement must be included in the written evaluation. In general, all data presentations for the background comparison (e.g., box plots, histograms, etc.) need to be included in the Chemicals of Concern Technical Memorandum.

3.2 Essential Nutrients Analysis

Constituents may be eliminated from the risk assessment if they are essential human nutrients (EPA 1989a). Commonly detected chemicals considered to be an essential part of the daily human diet (EPA, 1994d) include:

- Calcium
- Iron
- Magnesium
- Potassium
- Sodium.

A toxicologist may apply professional judgement and consult EPA to assess if other essential nutrients are within acceptable levels.

3.3 Chemicals of Concern Frequency of Detection Analysis

All metals above background levels and detected organic compounds are evaluated for frequency of detection. Compounds that are detected at a frequency of 5 percent or greater are considered potential OU-wide COCs. These compounds will be included in the concentration-toxicity screen (CTS) to identify compounds that could contribute significantly to total risk (EPA, 1994d) (Section 3.5). Compounds detected at less than 5 percent frequency are not considered characteristic of site contamination and the potential for exposure is low. Maximum concentrations of infrequently detected organic compounds and metals will be compared to risk-based concentrations (RBCs) as described in Section 3.4 to identify isolated or highly localized occurrences of high concentrations of toxic chemicals (i.e., hot spots) that could pose a risk if routine exposure were to occur. These chemicals will be retained as special-case COCs for separate evaluation in the risk assessment.

3.4 Risk-Based Concentration Comparison

Although frequency of detection is an important elimination criterion to prevent spurious data from biasing estimation of risks, an approach will be used to prevent small areas containing high contaminant levels from being eliminated. As a health-protective precaution to ensure that "hot spot" contaminants are not eliminated as COCs, all chemicals that satisfy the low frequency of detection criterion (less than 5% detection frequency) will be compared to RFETS-specific RBCs. RFETS-specific RBCs are the chemical-specific, pathway-specific, and medium-specific Programmatic Preliminary Remediation Goals (PPRGs) and are presented in Appendix C. These values were developed using approved risk assessment methodologies and represent screening levels which should be used in the risk-based comparison. If the maximum detected value of an infrequently detected contaminant exceeds 1,000 times its respective PPRG for any pathway, the chemical will be considered for inclusion as a special-case COC. A temporal analysis will then be conducted to determine whether to eliminate the chemical from further analysis or to retain it as a special-case COC. The temporal analysis applies to surface water, groundwater,

and air samples collected with specified frequency over a specified time period (for example, quarterly groundwater samples collected over 2 years).

The result of the temporal analysis will be identification of chemicals that are infrequently detected but that are detected at high concentrations and are associated with discrete events. These are termed special-case COCs and may warrant special consideration in any subsequent exposure assessment. That is, exposure may realistically occur only during specific events.

3.5 Concentration-Toxicity Screen

The purpose of a concentration-toxicity screen (CTS) is to reduce the number of chemicals carried through an HHRA (EPA, 1989a) and to focus the risk assessment on the chief contributors to potential risk. The criteria used in this screening step include the inherent toxicity of individual chemicals and the maximum detected concentration in each environmental medium for each OU. Toxicity values used to calculate individual risk factors are cancer slope factors (CSFs) for carcinogens, or the reciprocal of the reference dose (RfD) for screening chemicals that can produce noncarcinogenic effects. Thus, the risk factor for carcinogenic effects is the maximum detected concentration (or activity) multiplied by the CSF for that chemical. The risk factor for noncarcinogenic effects is the maximum detected concentration divided by the RfD for that chemical.

The following equation illustrates the process:

$$Rij = Cij * Tij \qquad (3.1)$$

where:

Rij = chemical-specific risk factor for chemical i in the medium j
Cij = maximum detected concentration of chemical i in the medium j
Tij = toxicity value (either the CSF or 1/RfD) for chemical i in the medium j

For chemicals with separate oral and inhalation toxicity values, the most conservative value should be used in the CTS unless the most conservative is inappropriate for a specific medium.

For example, only the oral toxicity value should be used for nonvolatile metals and radionuclides in groundwater. Chemicals without EPA-derived toxicity values cannot be screened by this procedure and will be advanced into the qualitative uncertainty analysis.

Carcinogenic and noncarcinogenic chemicals will be evaluated separately for each environmental medium. Some analytes, such as arsenic, have both noncarcinogenic and carcinogenic effects and are, therefore, included in both screens. Furthermore, a separate screen will be performed for radionuclides, due to differences in units of slope factors, [milligrams per kilogram per day^{-1} (mg/kg-day)$^{-1}$] vs. [picocurie^{-1} (pCi)$^{-1}$]. After calculating individual chemical-specific risk values for each medium, appropriate risk values will be summed to obtain the total risk factor (R*j*) for the medium. Individual chemical-specific values will then be divided by the total risk factor to derive a chemical-specific ratio (R*ij*/R*j*), providing an index of the relative risk contributed for each chemical. All chemicals that contribute less than 1 percent (ratio of 0.01) to the overall risk factor will be eliminated from further consideration. Consequently, chemicals advanced into the quantitative risk assessment will represent the COCs expected to contribute to the OU-related risk.

3.6 Professional Judgement

The last step of the COC selection process will involve applying additional professional judgement to ensure that hazardous chemicals are not unknowingly eliminated from the risk assessment and that only the most relevant COCs are retained. Professional judgement will be used to reevaluate the COCs identified based on the COC selection criteria described in sections 3.1 through 3.5.

In the case of organic chemicals—which are not compared to background, but which may also be evaluated spatially and temporally—it may be most efficient to apply professional judgement to those chemicals that are flagged in the CTS. For example, if toluene appears to be a risk driver according to the CTS, but low levels of toluene are dispersed throughout an OU without any indication of a source, one may suspect that factors other than point-source

contamination are responsible. If heretofore-unknown field or lab contamination were indicated through a more detailed investigation, then the argument for exclusion may be put forth with all relevant evidence documenting the case. To conduct such a detailed investigation for all detected organic chemicals prior to the CTS would be a poor use of resources.

3.7 Chemicals of Concern Technical Memorandum

A technical memorandum (TM) describing the COC identification process is required per the IAG. The submittal requirements for the COC TM include an introduction to the PCOCs determined via the background analysis, essential nutrient analysis, and summary tables illustrating the detection frequency analysis, CTS, and PPRG comparison.

Example formats for summary tables to be submitted as part of the TM are presented in Tables 3-1 through 3-4. Table 3-1 summarizes data for each analyte and should be provided for each applicable media. Tables 3-2 and 3-3 document the CTS for carcinogenic and noncarcinogenic chemicals respectively. Table 3-4 summarizes the COC selection process for each analyte. The following information is provided in this summary table: if the analyte is significantly above or below background; is it an essential nutrient; what is the detection frequency; did it pass the RBC screen; did it pass the temporal analysis; did it pass the CTS; is it a special-case COC; and, is the analyte a COC.

Table 3-1
Rocky Flats Environmental Technology Site:
COC Selection, Data Summary, for Environmental Media

Analyte	CRQL[a] (mg/kg)	Reported Detection Limit from RFEDS data (mg/kg)	Frequency of Detection	Minimum Concentration (mg/kg)	Maximum Concentration (mg/kg)	Mean Concentration (mg/kg)
Inorganics						
Organics						
Radionuclides[b]						

Notes:

a. CRQL = contract required quantitation limit
b. Reported in picocuries per gram or picocuries per liter
mg/kg = milligrams per kilogram or milligrams per litre

Table 3-2
Rocky Flats Environmental Technology Site:
COC Selection, Concentration-Toxicity Screen, for Carcinogenic Chemicals

Analyte	Weight of Evidence	Maximum Concentration	Toxicity Value (CSF)	Chemical-Specific Risk Factor (Ri)	Ratio of Ri/Rj
			Total Risk Factor (Rj)		

Weight-of-Evidence

A	Human Carcinogen (sufficient evidence of carcinogenicity in humans)
B	Probable Human Carcinogen (B1–limited evidence of carcinogenicity in humans; B2–sufficient evidence of carcinogenicity in animals with inadequate or lack of evidence in humans)
C	Possible Human Carcinogen (limited evidence of carcinogenicity in animals and inadequate or lack of human data)
D	Not Classifiable as to Human Carcinogenicity (inadequate or no evidence)
E	Evidence of Noncarcinogenicity for Humans (no evidence of carcinogenicity in adequate studies)

Table 3-3
Rocky Flats Environmental Technology Site:
COC Selection, Concentration-Toxicity Screen, for Noncarcinogenic Chemicals

Analyte	Maximum Concentration	Toxicity Value (1/RfD)	Chemical-Specific Risk Factor (Ri)	Ratio of Ri/Rj
		Total Risk Factor (Rj)		

Table 3-4
Rocky Flats Environmental Technology Site:
COC Selection, Rationale for Selecting COCs

Analyte	Background	Essential Nutrient	Frequency of Detection	RBC Screen	Temporal Analysis	Concentration-Toxicity Screen	Special-Case COC	COC
Inorganics								
Organics								
	N/A							
	N/A							
	N/A							
	N/A							
Radionuclides[a]								

Notes:

a Reported in picocuries per gram

4.0 COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT CONSERVATIVE SCREEN OF POTENTIAL CHEMICALS OF CONCERN

This section describes a conservative screen to be applied to data from each OU to ensure that the requirements of RCRA and the Colorado Hazardous Waste Act (CHWA) are met. The CDPHE conservative screen was developed as part of the data aggregation process used in an HHRA for RFETS by DOE, EPA, and CDPHE. The conservative screen will be used by DOE, EPA, and CDPHE to make a decision regarding no further action, voluntary corrective action, or further analysis through an HHRA.

The steps of the CDPHE conservative screen are:

- Perform a background analysis to identify PCOCs as metals and radionuclides significantly above background levels based on statistical evaluation (Gilbert, 1993), and organic target analytes detected above reporting limits.

- Delineate source areas that contain organic PCOCs above reporting limits and/or inorganic (or radionuclide) PCOCs (that were significantly above background) at concentrations above the arithmetic mean plus two standard deviations of the background data.

- Calculate the RBC ratio sum for each source area. The ratio of the maximum detected concentration or radioactivity to the RBC is calculated for each organic PCOC above reporting limits and each inorganic PCOC that occurs in the source area at a concentration or radioactivity above the background mean plus two standard deviations. The RBCs used in the CDPHE risk-based screen are presented in Appendix C and are based on the conservative RME residential receptor.

  Maximum detected concentrations or radioactivities in soil are identified from samples collected up to a depth of 12 feet which is the depth recommended for use by CDPHE. The chemical-specific and radionuclide-specific ratios are then summed for each medium, resulting in ratio sums for each medium. Ratio sums for soil and groundwater (if present) are also added to yield a total ratio sum for residential exposure (RME). If any ratio or ratio sum exceeds 1, the source area warrants further evaluation.

- Apply the CDPHE conservative screen decision criteria. Use the ratio sums to designate source areas as candidates for no further action or as candidates for further evaluation in the HHRA or possible early action. For source areas with

ratio sums less than 1, DOE may perform a dermal evaluation, and if appropriate, pursue a no further action alternative. For source areas with ratio sums between 1 and 100, and greater than 100, DOE may evaluate the source area further in the baseline HHRA and pursue a voluntary early action alternative, respectively.

- Define the areas of concern (AOCs) for the HHRA for review and approval by DOE, EPA, and CDPHE.

- Prepare the CDPHE conservative screen letter report to summarize the results of the preceding steps.

The flowchart in Figure 4-1 illustrates the CDPHE conservative screen. Each step is presented in the following sections.

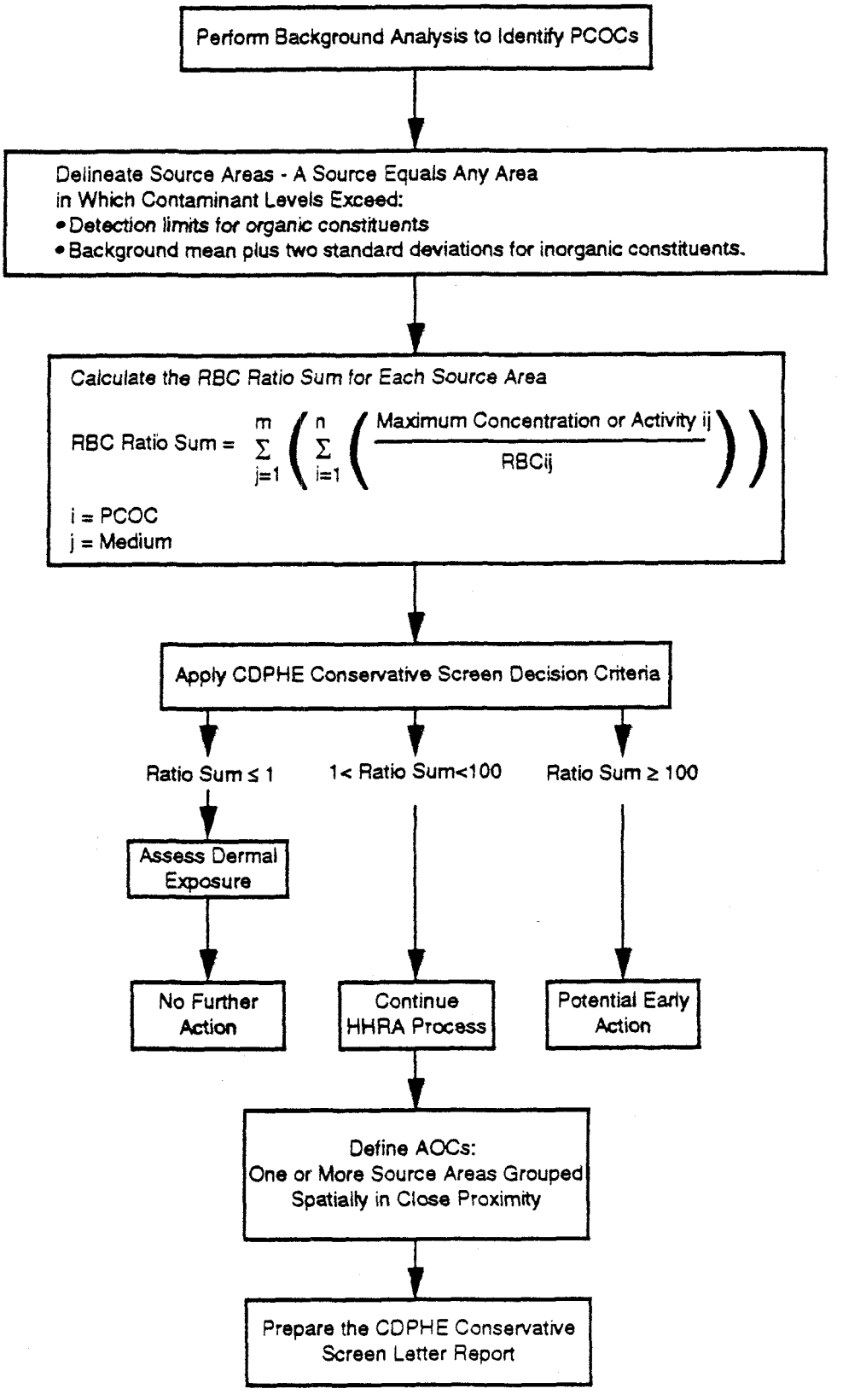
4.1 Perform Background Analyses

Identifying PCOCs from the background analysis described in Section 3.1 is the first step in the CDPHE conservative screen. The background analyses consist of the following statistical tests: the Gehan test, Quantile test, Slippage test, Student's t-test, and a $UTL_{99/99}$ comparison. These statistical methodologies are detailed in Appendix B.

4.2 Delineate Source Areas

The delineating of the nature and extent of contamination will include a description of source areas. For potential organic contaminants, the criterion for identifying source areas will be the detection limit; for potential inorganic contaminants or radionuclides, the criterion for identifying contaminant source areas will be the arithmetic mean of the appropriate background population plus two standard deviations. The spatial extent of contamination for each PCOC within a source area may vary for each source because multiple contaminants may be detected in multiple media within each source. Therefore, professional judgement will be used to define a source as all contamination that can reasonably be associated with the area based on historical use, site characterization, contaminant types, concentrations, affected media, and rates of migration.

Figure 4-1 CDPHE Conservative Screen



DOE will prepare one or more maps of the source areas (depending on the complexity of the OU) and submit these maps to EPA and CDPHE for review and approval. A meeting of the three agencies may be required to present the rationale for identifying sources with complex media interactions or multiple potential contaminants.

4.3 Calculate the RBC Ratio Sum

Each potential contaminant in each medium has an associated medium-specific RBC that is calculated based on the following assumptions:

- Direct residential exposure
- Direct ingestion and inhalation exposure pathways
- A carcinogenic risk of 10^{-6} and a noncarcinogenic hazard quotient of 1.0.

For each source identified, the maximum detected value for each potential contaminant in each medium should be determined. If elevated non-detect values are present (e.g., qualified with a U) that exceed the maximum detected value, these should not be used as maximum values. Professional judgement should be used to examine the reasonableness of the maximum value within the data set. For example, values that are three orders of magnitude above the other data points may have been reported in incorrect units.

Each contaminant-specific maximum concentration should then be divided by its corresponding RBC with separate calculations performed for carcinogens and noncarcinogens. The PPRGs presented in Appendix C will be used as RBCs. The maximum concentration to RBC ratios for the source areas should then be summed for all PCOCs for each medium and then across all media within a source. This sum is referred to as the ratio sum and is the basis for remedial decisions for each source area under the CHWA. The ratio sum step is illustrated in Figure 4-1. Table 4-1 is provided as an example table shell for presenting the ratio sum calculation.

Table 4-1
CDPHE Conservative Screen Ration Sums for Source Area
Soil, Surface to 12 Feet Depth

COC	Maximum Concentration or Activity	Location of Maximum Concentration	Depth of Maximum Concentration (ft.)	RBCs Carcino-genic	RBCs Noncarcino-genic	Max Conc./RBC Carcinogen	Max Conc./RB Noncar-cinogen
Organics (mg/kg)							
Contaminant 1							
Contaminant 2							
Contaminant 3							
Contaminant n							
Pesticides PCBs (mg/kg)							
Contaminant 1							
Contaminant 2							
Contaminant 3							
Contaminant n							
Inorganics (mg/kg)							
Contaminant 1							
Contaminant 2							
Contaminant 3							
Contaminant n							
Radionuclides (pCi/kg)							
					Ratio Sum		

4.4 Apply CDPHE Conservative Screen Decision Criteria

The decision criteria that will be used to evaluate source areas are illustrated in Figure 4-1. These criteria should be applied to each identified source area. The total ratio sums for carcinogenic or noncarcinogenic effects are an indication of potential risks to the receptors, assuming long-term exposure to maximum detected concentrations of PCOCs in soil and groundwater. For carcinogens, a total ratio sum of less than one indicates a potential total excess lifetime cancer risk of less than 10^{-6} (1 in 1,000,000) from long-term exposure to the maximum concentrations of PCOCs in that source area. A total ratio sum for carcinogens due to maximum concentrations that is greater than one but less than 100 indicates a potential total excess lifetime cancer risk between 10^{-4} (1 in 10,000) and 10^{-6}. This is the target cancer risk range that the EPA has adopted to guide remedial decisions at hazardous waste sites using average contaminant concentrations. A total ratio sum for carcinogens that is greater than 100 indicates a potentially unacceptable cancer risk from long-term exposure to maximum detected concentrations. For noncarcinogens, a ratio or ratio sum less than or equal to one indicates no toxic effects are expected. A noncarcinogenic total ratio greater than one indicates that there may be cause for concern for noncarcinogenic effects.

This risk-based screen is conservative because it assumes that a long-term resident will be routinely exposed to the maximum concentrations of contaminants found in soil and groundwater. The screen does not confirm that an actual risk exists. Ratio sums greater than one or 100 indicate that the area warrants further evaluation, but the ratios do not indicate that an actual health threat is present.

If either the carcinogenic or noncarcinogenic total ratio sum is greater than 100, that source area may be identified by DOE as a candidate for an early action. Source areas with ratio sums between one and 100 will be evaluated further in the baseline HHRA. If both the carcinogenic and noncarcinogenic total ratio sums are less than one, the source area is a

candidate for no further action based on human health risk. In these cases, the risk from dermal exposure is evaluated to confirm that the ratio sums including dermal exposure are still less than one.

4.5 Define AOCs for the HHRA

One or several sources grouped spatially in close proximity are considered an AOC. This determination is made after the source areas have been screened by the CDPHE conservative screen. If source areas are clearly separated, then each is potentially an AOC. Those source areas that overlap or are adjacent to each other may be grouped using professional judgement.

4.6 Prepare the CDPHE Conservative Screen Letter Report

The CDPHE conservative screen letter report will include map and text summaries of source areas and AOCs, and tabular results of the CDPHE conservative screen. The letter report will serve as the basis for discussion and consensus among DOE, EPA, and CDPHE to proceed with the HHRA given the exposure areas and contaminants identified. The report will include:

- Source area maps
- Tables of all PCOCs, listing their RBCs, the maximum concentration/RBC ratio, and ratio sum
- Brief discussion of the decision criteria
- Map(s) of AOCs
- Professional judgement
- Background comparison (if applicable).

5.0 EXPOSURE ASSESSMENT

Exposure assessment for an HHRA is the quantitative or qualitative evaluation of contact between a human receptor and chemical(s) or physical agent(s). This assessment:

- Describes the intensity, frequency, and duration of contact
- Evaluates the rates at which the chemical crosses the boundary into the receptor
- Evaluates the resulting amount of the chemical that actually crosses the boundary (dose) and/or the amount absorbed (internal dose).

The primary purpose of an exposure assessment as part of an HHRA is to estimate total dose for a receptor in a given exposure area, which is combined with chemical-specific dose-response data used to estimate risk.

The exposure area is the area in which a potential receptor can reasonably be expected to contact COCs over a specified exposure duration. An exposure area can vary in size, depending on site-specific conditions and potential receptors. At some sites, the exposure area is considered to be the entire site; at others, the exposure area is only a portion of the site. For RFETS, the agreed to AOCs are considered the exposure areas and are defined as one or several sources grouped spatially in close proximity.

The process of a chemical entering the body occurs in two steps. First an exposure, or contact with the chemical, must take place, and second, actual entry into the receptor must occur. After entry into the receptor the amount of the chemical absorbed by the body (internal dose) can be estimated.

The two major processes by which a chemical can cross the boundary from outside to inside the body are intake and uptake. Intake involves physically moving the chemical through an opening in the body such as the mouth or nose and usually occurs via inhalation, eating, or drinking. The chemical is normally contained in a carrier medium such as air, food, or drink. The estimate of how much of the chemical enters the body focuses on how much of the carrier

medium enters. The uptake process of a chemical entering the body involves absorption of the chemical through the skin or other exposed tissue such as the eye. Although the chemical is normally contained in a medium, the medium typically is not absorbed at the same rate as the chemical. Therefore, the estimates of the amount of chemical entering the body are greatly affected by such factors as the concentration gradient across the boundary and the permeability of the barrier.

The following sections describe the exposure assessment process and documentation.

5.1 Identifying Populations and Land Use

Potentially exposed populations that are applicable to the site should be characterized. Additionally, potential land uses should be identified. Current and future exposure scenarios can then be developed that realistically characterize the site and allow an exposure assessment to be completed. The RFETS CWP, (CWP 1995), contains a site description that includes present and future population information, geographic setting and topography, and geological and hydrological setting. Also local demographics information is provided in the *1994 Population, Economic, and Land Use Data Base for the Rocky Flats Environmental Technology Site*, (DOE, 1994c).

Currently, onsite workers make up the only potentially exposed population for current onsite receptors. It is not expected that current or future offsite receptors will be addressed by each individual OU. Rather, exposure to all offsite receptors will be addressed in one risk assessment (assumed to be OU3, offsite areas). Future onsite receptors include: an industrial worker, office worker, construction worker, ecological researcher, and an open space receptor. These receptors do not include an onsite resident, and are consistent with the preliminary alternatives and recommendations of the RFETS future site use working group.

5.2 Selecting Exposure Scenarios

An exposure scenario generally includes facts, data, assumptions, inferences, and sometimes professional judgement about the following:

- Physical setting where exposure would take place
- Exposure pathway(s) from source(s) to exposed individual(s)
- Characterization of the chemical(s) such as amounts, locations, environmental pathways, fate of chemical in environment, etc.
- Identification of the exposed individual(s) or population(s), and the profile of contact with the chemical(s)
- Assumptions about the transfer of the chemical to the receptor.

Current and future human populations on and near the RFETS are potential candidates for evaluation based on their likelihood of exposure to site-related COCs. EPA guidance does not require an exhaustive assessment of every potential receptor and exposure scenario (EPA, 1992c). Rather, the highest potential exposures that are reasonably expected to occur should be evaluated, along with an assessment of any associated uncertainty (EPA, 1989a). However, potential receptors will be identified and evaluated to ensure that the important exposure pathways and receptors have been included.

Some potential receptors that have been routinely identified and/or assessed in the past will no longer always need to be quantitatively assessed. These receptors are: a future onsite gravel miner, a future onsite residential receptor, and current and future offsite receptors. It appears likely that future mining operations will only be feasible in the western portions of the RFETS buffer zone. This area is outside OU boundaries except for OU11 and therefore mining will not need to be assessed in the other OUs. Based on the most current information gathered by the RFETS future site use working group, future onsite residential receptors are outside the range of what is reasonable for the future use of the RFETS. Therefore, future onsite residential receptors will not need to be quantitatively assessed. Finally, offsite receptors are exposed to

the cumulative effects of COCs released from the entire RFETS. Therefore, limiting the exposures of these receptors to individual OU COCs does not provide a complete assessment of the potential risks and should not be provided.

The approach to eliminating these potential receptors from further evaluation is consistent with agreements made between DOE, EPA and CDPHE. It is also consistent with the recommendations of the RFETS future site use working group.

5.3 Refining Conceptual Site Model and Pathway Analysis

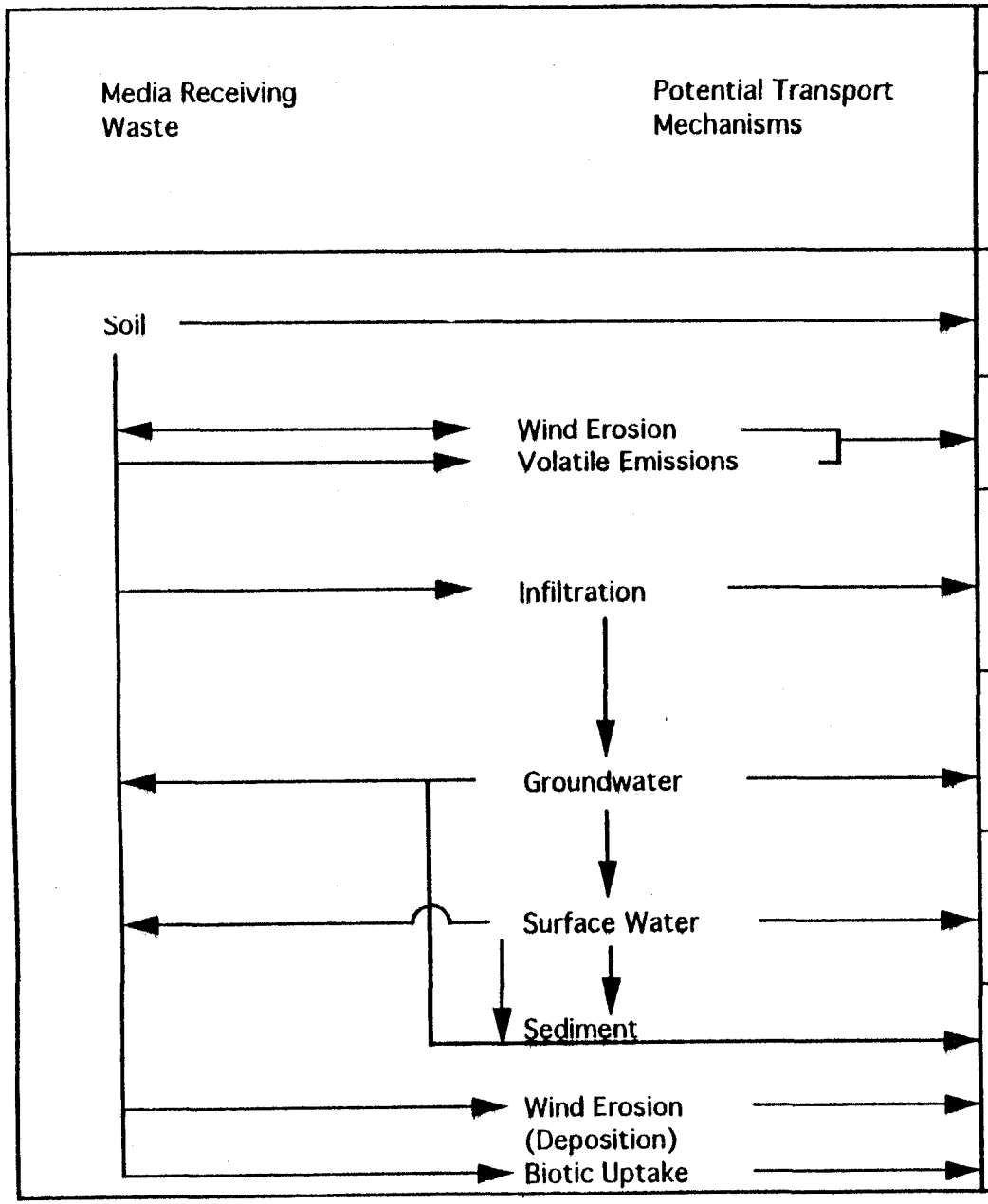
Information concerning waste sources, waste constituent release and transport mechanisms, and locations of potentially exposed receptors is used to develop a conceptual understanding of the site in terms of potential human exposure pathways.

The conceptual site model (CSM) is a schematic representation of the contaminant source areas, contaminant release mechanisms, environmental transport media, potential human intake routes, and potential human receptors. The purpose of the CSM is to:

- Provide a framework for problem definition
- Identify exposure pathways that may result in human health risks
- Aid in identifying data gaps
- Aid in identifying effective clean-up measures, if necessary, that are targeted at significant contaminant sources and exposure pathways.

Figure 5-1 shows a generalized CSM for potential human exposure pathways. As illustrated in this example, primary, secondary, and negligible or incomplete pathways are identified for

Figure 5-1 Generalized Conceptual Site Model for HHRA



Exposure		Human Receptors		
Media	Route	Residential	Industrial/ Commercial	Recreational
Soils	Ingestion	o	o	o
	Dermal	o	o	o
	External	o	o	o
Air (Dust/ Volatiles)	Inhalation	o	o	o
	External	-	-	-
Groundwater	Ingestion	o	o	o
	Inhalation	s	s	s
	Dermal	s	s	s
	External	-	-	-
Surface Water	Ingestion	o	o	o
	Inhalation	s	s	s
	Dermal	s	s	s
	External	-	-	-
Sediment	Ingestion	s	-	s
	Dermal	-	-	-
	External	s	-	s
Biota	Dairy	-	-	-
	Beef	-	-	-
	Game	-	-	o
	Fish	o	-	o
	Plant/Crop	o	-	o

o Primary Pathway
s Secondary Pathway
- Negligable/Insignificant Pathway

each potential human receptor. Primary pathways can be defined as resulting in potentially complete and significant exposure, and secondary pathways as potentially complete and relatively insignificant exposure. Both primary and secondary pathways should be quantitatively addressed in the HHRA. Quantitatively addressing primary and secondary exposure pathways will provide for risk estimates that do not underestimate actual risks. Negligible or incomplete exposure pathways are designated in the example CSM, however, these pathways are not quantitatively addressed in the HHRA but should be qualitatively discussed.

Significant pathways are those that involve relatively direct exposure or only moderately reduced concentrations due to contaminant fate and transport. In contrast, insignificant pathways are those that are expected to result in exposure concentrations one or more orders of magnitude lower than significant exposure pathways. In addition, negligible or incomplete pathways are those where fate and transport are expected to reduce contaminant concentrations by several orders of magnitude or more in comparison to significant exposure pathways.

5.3.1 Identifying Sources and Release Mechanisms

As indicated in the CSM example in Figure 5-1, the contamination is traced from primary source to potential human receptor. First, the primary release mechanisms are identified for the primary source(s), then the resulting secondary sources are identified, and finally, the secondary release mechanisms (as appropriate) are described. Subsequent sources and release mechanisms are identified until the exposure route for the contaminant is reached. Potential human receptors are identified, and the probable significance of the potential exposure for each receptor and exposure route is determined.

5.3.2 Identifying Complete Pathways

As previously discussed, the CSM aids in identifying potentially complete pathways for the HHRA. An exposure pathway describes a specific environmental pathway by which an individual receptor could be exposed to contaminants present at or originating from a site. An exposure pathway includes five necessary elements:

- Source of chemical(s)
- Mechanism of chemical release
- Environmental transport medium
- Exposure point
- A human intake route.

Each of these five elements must be present for an exposure pathway to be complete. Then all potentially complete pathways will be discussed, by scenario, in the HHRA. An incomplete pathway means that no human exposure can occur. Only potentially complete and relevant pathways need be addressed in HHRAs for the RFETS.

5.4 Identifying Exposure Area and Exposure Point Concentrations

After AOCs and COCs have been identified, exposure point concentrations are estimated for each COC in each environmental medium. All COC data within the AOC will be aggregated over the appropriate exposure area. Steps in the exposure area procedure include.

- Determine the size of the exposure area for each scenario by considering the receptors, the toxicity of the COC, and exposure pathways. Default exposure areas for RFETS are 50 acres for ecological researchers or open space receptors and 30 acres for commercial industrial workers.

- Plot all COC data, including data below background or detection limit, on a map of the OU.

- Consult with toxicologists and health physicists from DOE, EPA, and CDPHE to properly place grids of exposure areas over each AOC.

- If an exposure area is larger than the appropriate grid(s), identify the exposure area representing the highest risk by considering COC concentrations, contaminated environmental media, and potential exposure pathways. If the exposure area associated with the highest risk within the OU cannot be readily defined, several exposure areas may need to be analyzed. Analyze data within the exposure area using the following procedure:

  — Using the complete OU data set, determine the statistical distribution (normal or lognormal) for each COC in each environmental medium.

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- Plot the data in a histogram graph showing frequency of detection versus concentration.

- Use EPA's *Supplemental Guidance to RAGS: Calculating the Concentration Term* (EPA, 1992d) to calculate the 95th percent upper confidence limit (95% UCL) of the arithmetic mean over each exposure area for each COC. Guidance for treatment of data sets with nondetects is presented in Section 5.3.3 of RAGS. If the COC data are lognormally distributed, use Supplemental Guidance to RAGS (EPA, 1992d) highlight 5. If the COC data are normally distributed or are determined to be non-parametric, use highlight 6. The guidance states that calculation of the 95% UCL using data sets with fewer than 10 samples per exposure area provides a poor estimate of the mean concentration. Data sets with 20 to 30 samples per exposure area provide a fairly consistent estimate of the mean. For limited amounts of data, the 95% UCL can be greater than the highest measured concentration. In these cases, the highest measured value should be used as the concentration term. A professional statistician should be consulted for questions regarding the treatment of nondetects in the data set and calculation of the exposure point concentration. Uncertainties in the estimates of the mean concentrations will be addressed in the uncertainty analysis. On a case-by-case basis, with the approval of the regulators, geostatistics may be utilized to evaluate spatial continuity of data.

5.5 Identifying Exposure Equations and Parameters

Identify exposure equations and parameters for the complete pathways discussed in Section 5.3. Use the exposure point concentrations of chemicals in the various media (discussed in Section 4) to estimate the potential human intake of those chemicals via each exposure pathway. Intakes are expressed in terms of milligrams of chemical ingested, inhaled or dermally absorbed per kilogram of body weight per day (mg/kg-day). Intakes are calculated following guidance in RAGS (EPA, 1989a), the *Exposure Factors Handbook* (EPA, 1989b), other EPA guidance documents as appropriate. Appendix D provides RFETS site-specific exposure factors that are incorporated into the intake equations. Intakes are estimated using the Appendix D that include body weight, inhalation volume, ingestion rates, soil or food matrix effects, and frequency and duration of exposure.

Calculations are conducted to identify the central tendency (CT) value for intake and the reasonable maximum exposure (RME) value for intake. The tables in Appendix D provide both CT and RME values and provide appropriate footnotes to assist the risk assessor. The CT value for intake is estimated by using CT values (e.g., mean and median) for exposure variables. The RME is estimated by selecting values for exposure variables so that the combination of all variables results in the maximum exposure that can reasonably be expected to occur at the site. Both calculations use the 95% UCL exposure point concentration (EPA, 1992d).

The general equation for calculating intake in terms of mg/kg-day is:

$$\text{Total Intake} = \frac{C \times IR \times EF \times ED}{BW \times AT} \qquad (5.1)$$

where:

Total Intake	=	mg/kg-day
C	=	Concentration in mg/vol
IR	=	Intake rate in vol/day
EF	=	Exposure frequency in days/years
ED	=	Exposure duration in years
BW	=	Body weight in kg
AT	=	Averaging time in days

For noncarcinogenic chemicals, intakes are calculated by averaging over the period of exposure to yield an average daily intake. For carcinogens, intakes are calculated by averaging the total cumulative dose over a lifetime, yielding "lifetime average daily intake." Different averaging times are used for carcinogens and noncarcinogens because it is thought that their effects occur by different mechanisms. The approach for carcinogens is based on the current scientific opinion that a high dose received over a short period of time is equivalent to a corresponding low dose spread over a lifetime. Therefore, regardless of exposure duration, the intake of a carcinogen is averaged over a 70-year lifetime (EPA, 1989a). Equation 5.1 is used to calculate intakes of radionuclides except that the denominator (body weight x averaging time) is excluded. Intakes of noncarcinogens are averaged over the period of exposure because

potential effects would be expected to occur during the period of exposure. The following are generalized pathway-specific equations in use at RFETS.

Ingestion of Water

$$\text{Intake (mg/kg-day)} = \frac{CW \times IR \times EF \times ED}{BW \times AT} \qquad (5.2)$$

where:

CW = Chemical concentration in water (mg/L)
IR = Ingestion rate (L/day)
EF = Exposure frequency (days/year)
ED = Exposure duration (years)
BW = Body weight (kg)
AT = Averaging time (period over which exposure is averaged - days)

For calculation of radionuclide intakes, the concentration is expressed in pCi/L, and the expression is not divided by body weight and averaging time. The intake for radionuclides is expressed in pCi.

Dermal Contact with Water

The equation used for dermal contact with contaminants in water is presented below. This equation calculates the actual absorbed dose (i.e., intake, not the amount of chemical that comes in contact with the skin.

$$\text{Absorbed Dose (mg/kg-day)} = \frac{CW \times SA \times PC \times ET \times EF \times ED \times CF}{BW \times AT} \qquad (5.3)$$

where:

CW = Chemical concentration in water (mg/L)
SA = Skin surface area available for contact (cm^2)
PC = Chemical-specific dermal permeability constant (cm/hour)
ET = Exposure time (hours/days)
EF = Exposure frequency (days/years)
ED = Exposure duration (years
CF = Volumetric conversion factor for water (1 L/1000 cm^3)
BW = Body weight (kg)
AT = Averaging time (period over which exposure is averaged - days)

Inhalation of Airborne Contaminants

Airborne contaminants may be either in the vapor phase or, in the case of metals and radionuclides, in particulate form. Dermal absorption of vapor-phase contaminants is considered to be negligible in proportion to inhalation intakes and, therefore, is disregarded in accordance with RAGS (EPA, 1989a). The following equation is used:

$$\text{Intake (mg/kg-day)} = \frac{\text{CA x IR x EF x ED}}{\text{BW x AT}} \qquad (5.4)$$

where:

CA = Contaminant concentration in air (mg/m^3)
IR = Inhalation rate (m^3/day)
EF = Exposure frequency (days/year)
ED = Exposure duration (years)
BW = Body weight (kg)
AT = Averaging time (period over which exposure is averaged - days)

For calculation of intakes from inhalation of particulates, only the fraction of the particulate concentration in air that is considered to be respirable ($< 10\ \mu$m) is evaluated. The respiratory model developed by the International Commission on Radiological Protection indicates that particles with sizes above 10 μm are relatively unimportant contributors to internal dose (NCRP, 1985). For calculation of radionuclide intakes, the concentration is expressed in pCi/m^3 and the expression is not divided by body weight and averaging time. The intake for radionuclides is expressed in pCi.

Incidental Ingestion of Soil or Sediments

The following equation is used in calculating the intake from incidental ingestion of contaminants in soil or sediments:

$$\text{Intake (mg/kg-day)} = \frac{\text{CS x IR x CF x FI x EF x ED}}{\text{BW x AT}} \qquad (5.5)$$

where:

CS = Chemical concentrations in soil (mg/kg)
IR = Ingestion rate (mg soil/day)
CF = Conversion factor (10^{-6} kg/mg)
FI = Fraction ingested from contaminated source (unitless)
EF = Exposure frequency (days/years)
ED = Exposure duration (years)
BW = Body weight (kg)
AT = Averaging time (period over which exposure is averaged - days)

For calculation of radionuclide intakes, the concentration is expressed in pCi/kg, and the expression is not divided by body weight and averaging time. The intake for radionuclides is expressed in pCi.

Dermal Contact With Soil or Sediments

The exposure from dermal contact with contaminants in soil and sediments is calculated using the following equation which results in an estimate of the absorbed dose, not the amount of chemical in contact with the skin (i.e., intake):

$$\text{Absorbed Dose (mg/kg-day)} = \frac{CS \times CF \times SA \times AF \times ABS \times EF \times ED}{BW \times AT} \qquad (5.6)$$

where:

CS = Chemical concentration in soil or sediments (mg/kg)
CF = Conversion factor (10^{-6} kg/mg)
SA = Skin surface area available for contact (cm^2/event)
AF = Soil to skin adherence factor (mg/cm^2)
ABS = Absorption factor (unitless)
EF = Exposure frequency (events/year)
ED = Exposure duration (years)
BW = Body weight (kg)
AT = Averaging time (period over which exposure is averaged - days)

Ingestion of Garden Fruits and Vegetables

The contaminant intakes for ingestion of garden produce are calculated using the following equation:

$$\text{Intake (mg/kg-day)} = \frac{CF \times IR \times FI \times EF \times ED}{BW \times AT} \quad (5.7)$$

where:

CF = Contaminant concentration in food (mg/kg)
IR = Ingestion rate (kg/day)
FI = Fraction ingested from contaminated source (unitless)
EF = Exposure frequency (days/year)
ED = Exposure duration (years)
BW = Body weight (kg)
AT = Averaging time (period over which exposure is averaged - days)

For calculation of radionuclide intakes, the concentration is expressed in pCi/kg, and the expression is not divided by body weight and averaging time. The intake for radionuclides is expressed in pCi.

External Radiation Exposure

Radionuclide intakes for external exposure are calculated using the following equation:

$$\text{Intake (pCi)} = C \times ED \times (1-Se) \times Te \quad (5.8)$$

where:

C = Isotope activity (pCi/g)
ED = Exposure duration (years)
Se = Gamma shielding factor (unitless)
Te = Gamma exposure factor (unitless)

Omitting chemical concentrations or dose from the intake equation yields an "intake factor" that is constant for the respective exposure pathway and receptor. The intake factor can then be multiplied by the concentration or dose of each chemical to obtain the pathway and receptor-

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specific intake of that chemical. Intake factors are calculated separately for each applicable exposed receptor and exposure pathway. Contact rates, such as dermal contact, caloric intake and inhalation (but not soil ingestion) are approximately proportional to body weight. Body weight is not exactly proportional to surface area and age-specific body weight/inhalation rates differ by factors of two or less. However, these differences are assumed to be negligible when compared to the other uncertainties associated with risk assessment.

5.6 Developing an Exposure Assessment Technical Memorandum

The Exposure Assessment Technical Memorandum (EATM) describes present, future, potential, and reasonable use exposure scenarios to be evaluated and identifies reasonable maximum intake parameters for estimating contaminant intake via these pathways. The EATM is normally submitted prior to initiating the exposure assessment calculations.

The contents of the EATM include:

- Population, land use, and current and future human exposure scenarios
- Complete exposure pathways identified by the CSM
- The route(s) of contaminant intake
- Maps of AOCs and grid placement
- Intake equations and parameters for each potentially contaminated medium, such as soil, water, and air.

The EATM does not quantify COC intake. The magnitude of exposure is dependent on the COC concentration at the exposure points, which will be estimated based on the analytical results of the OU Phase I Site Investigation and fate and transport modeling, as appropriate.

5.7 Using Fate and Transport Modeling

If concentrations in the media cannot be measured, they can frequently be estimated indirectly by using fate and transport modeling. To accomplish this, fate and transport models use a combination of general relationships and situation-specific information to estimate concentrations of chemicals in different environmental media, the distribution of concentrations over space and time, indoor air levels of chemicals, concentrations in foods, and so forth. Because models rely on indirect measurements and data remote from the point of contact, statistically valid analytical measurements take precedence if discrepancies arise.

The term model refers to computer codes or a set of equations that can be used to represent site conditions and the transport of COCs through soil gas, groundwater, surface water, and air. The models incorporate site-specific data and interpretations of and estimates derived from site-specific data. The combination of a computer code and site-specific data is generally referred to as a site-specific model.

Models selected should be capable of incorporating key COC transport and transformation processes and simulating the important domain characteristics and material/fluid properties. The following five categories should be considered when selecting models for use:

- Ability to adequately simulate RFETS conditions
- Ability to satisfy the objectives of the study
- Verification of the model using published analytical equations
- Documentation, peer-review, and availability
- Practicality and cost-effectiveness.

Considerations for implementing a model include:

- Availability of and confidence in input data that will support the model
- Availability of the model
- Degree and nature of documentation
- Extent of peer review of the model
- Nature of model verification and validation and testing

- Computer systems on which the model has been used
- User familiarity with the model.

The following subsections describe modeling that may be used in an HHRA.

5.7.1 Using the CSM to Determine Modeling Needs and Objectives

The CSM evaluates exposure pathways by their potential contribution to exposure and classifies them as significant, insignificant, and negligible or incomplete. Significant pathways should be examined to identify the need for modeling. Pathways involving direct exposure to sources may use measured source data directly and do not require modeling. Pathways with multiple release mechanisms may require fate and transport modeling (e.g., resuspension of subsequent airborne contaminant soil and transport offsite).

Many fate and transport models are available for use and the listed categories and considerations discussed in section 5.7 should be consulted prior to the final selection of a specific model(s). The goal of fate and transport modeling is to simulate contaminant migration from source areas in soils, groundwater, surface water, sediments, and air to potential on-site and off-site receptors. The results of the modeling are then used in the HHRA of the BRA, and may also be used for the EE.

5.7.2 Overview of Models and Data Needs

The following sections provide an overview of the modeling specific to contaminants in soil gas, groundwater, surface water, and air. This document does not discuss specific models; however, when specific models are selected for use at RFETS, it is important to identify and document the assumptions and limitations associated with each model and its application. Use of modeling should be documented in an OU-specific modeling TM as discussed further in section 5.8. The following four sections discuss soil gas transport, groundwater, surface water, and air modeling.

5.7.2.1 Soil-Gas Transport - The objective of soil-gas modeling is to predict the transport and resulting concentrations in air of contaminants through the soil-gas pathway. Such predictions will be formulated to provide the information necessary to perform an HHRA. Normally the highest concentrations of contaminants from the soil gas pathway are inside of a building, therefore, part of the modeling investigation should be directed at characterizing the geotechnical suitability of the site for construction of buildings associated with future human receptors. Examples of the data needed for a soil gas model(s) that may or may not require assumptions include:

- Properties of the site such as soil porosity, water content, and hydraulic conductivity
- Environmental properties such as relative humidity
- Building characteristics such as pressurization and ventilation rate
- Chemical-specific properties such as vadose zone concentration, groundwater concentration, solubility, Henry's law constant, and biodegradation rate.

5.7.2.2 Groundwater - A hydrogeological conceptual model provides a description of the primary processes that control the movement of solutes in the subsurface. Such processes include groundwater flow rates and directions, solute release rates and timing, recharge and discharge rates, dispersion, degradation rates, and adsorption. Vadose zone and groundwater modeling should consider site-specific conditions, the location(s) of the groundwater flow, recharge and discharge, the primary source(s) of contamination, the distribution of boundary conditions, and material types. Examples of data required for the modeling effort include:

- Horizontal and vertical hydraulic conductivity
- Specific storativity
- Porosity
- Molecular dispersion
- Residual and saturated moisture content.

5.7.2.3 Surface Water - The purpose of surface water modeling is to estimate the potential concentration of contaminants in associated surface water locations at RFETS. The potential for future transport of contaminants by surface water erosion can be evaluated using

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empirical mathematical models. Because of the dispersed nature of drainage patterns associated with overland flow, nonpoint sources associated with overland flow are very difficult to monitor using conventional methods. Nonpoint source models consist of equations to predict surface water runoff supplemented with methods to calculate sediment movement. Combined, the two components describe contaminant transport associated with overland flow and nonpoint sources. The equations describe total contaminant concentrations in overland flow (dissolved, adsorbed and solid components), and total contaminant mass loading. Assumptions associated with surface water modeling include:

- Area of site that affects surface water
- Area of contaminated soils
- Contaminant concentrations in soil
- Soil erodibility factor
- Cover/management factor
- Length-slope factor
- Rainfall factor
- Seasonal water flow.

5.7.2.4 Air - The objective of air modeling is to provide estimates of emissions, dispersion, surface deposition, and fate of contaminants released from the site. Both near-field and far-field scenarios should be developed for the site. Far-field models are more complex and include most of the requirements of near-field models, with the addition of transport, dispersion and deposition of contaminants. Site characteristics that require simulation include:

- Meteorological conditions
- Dispersion assumptions
- Special conditions
- Time domain
- Terrain characteristics.

Conditions at the receptor which must also be represented by the model include:

- Height
- Location
- Exposure pathways

- Occupancy factors
- Consumption or usage.

5.8 Documenting Fate and Transport Modeling

The fate and transport modeling TM is prepared as part of the HHRA process. The TM provides a brief description of the RFETS conditions, emphasizing those conditions that have greater impact on the modeling results. It documents the specific criteria that were used to select the models, and as appropriate, why the criteria are critical. The TM then describes the specific model(s) selected for use, and to which media and pathways the model(s) are applicable. Specific data requirements for each model should be identified, and finally, a data summary of the model(s) parameters should be included.

5.9 Documenting the Exposure Assessment

After the appropriate modeling has been completed, the results need to be documented in the exposure assessment. The following subsections discuss how modeling results are incorporated.

5.9.1 Documenting Fate and Transport Modeling Results

The results of fate and transport modeling for the associated medium should be documented along with critical assumptions that are made. Modeling can be useful to derive contaminant concentrations in groundwater, surface water, and air. The results are usually summarized in a format consistent with the selected RME values and that can be directly incorporated into the intake equations; or, a 95% UCL value can be calculated.

5.9.2 Documenting Biouptake Results

Modeling results applicable to biouptake of contaminants through ingestion of fruits, vegetables, meat, milk, fish, and shellfish should also be documented in the exposure assessment. As discussed in RAGS, the primary items of concern for exposure by ingestion of COCs that have accumulated in food are:

- Fish and shellfish
- Vegetables and other produce
- Meat, eggs, and dairy products (domestic and game species).

To incorporate modeling results and determine pathway-specific and COC-specific biouptake, the equations in RAGS should be consulted.

5.10 Calculating Intakes

As discussed in Section 5.5, calculations are conducted for CT and RME values for intake (EPA, 1992d). The RME is estimated by selecting various input values for exposure variables so that the combination of all variables in the intake equations results in the RME that can be expected to occur. This approach usually results in individual intake variables that are not at their maximum; however, when combined with other variables, yields estimates of RME. Site-specific parameters for each receptor, pathway, and respective intake equation are identified in Appendix D and should be documented in the exposure assessment. The parameters can be summarized in tables to make the correlation between pathway-specific intake equations and the correct parameters obvious. During the exposure assessment, specific probability distributions for each exposure parameter may also be identified for use in the quantitative uncertainty analysis.

Table 5-1 provides an example of an intake factor equation, along with the respective parameters for inhalation of particulates. Exposure parameters specific to RFETS have been developed to provide information necessary to calculate a CT and RME values for intake. These values are found in Appendix D and should be used unless alternate values can be justified and are approved by DOE, EPA, and CDPHE.

Combining situation-specific input parameters and COC concentrations in respective intake equations, yields values for receptor intakes that can then be used to determine potential health risk. After the intake values are calculated, they may be presented in tabular form, such as in Table 5-2. In Table 5-2, pathways are presented in column headers and the rows contain COCs. Thus, each intake presented is identified with a specific pathway and a specific COC. Organize intake tables and associated risk tables in the same manner to facilitate reading and checking.

Table 5-1
Ingestion of Soil/Dust
Future Onsite Office Worker

Intake Factor = $\frac{IR \times FI \times AF \times EF \times ED}{BW \times AT}$			
Parameter		**Central Tendency**	**RME**
IR =	Inhalation rate (mg/day)	5	50
FI =	Fraction ingested (unitless)	0.9	1.0
AF =	Absorption factor (matrix effect in GI tract) (unitless)	Chemical Specific	Chemical Specific
EF =	Exposure frequency (day/yr)	219	250
ED =	Exposure duration (yr)	4	25
BW =	Body weight (kg)	70	70
AT =	Averaging time (days)		
	Noncarcinogenic	1460	9125
	Carcinogenic	25550	25550

Note: See Appendix D for all RFETS site-specific exposure factors

Table 5-2
COC Intakes

COC	Pathway A (mg/kg-d)[a]	Pathway B (mg/kg-d)[a]	Pathway C (mg/kg-d)[a]	Pathway N (mg/kg-d)[a]
COC 1				
COC 2				
COC 3				
COC n				

[a] *Units equal mg/kg-day, radionuclide units equal pCi*

6.0 TOXICITY ASSESSMENT

Toxicity values are used to characterize risk and toxicity profiles summarize toxicological information for radioactive and nonradioactive COCs. Consistent with RAGS (EPA, 1989a), the toxicity information is summarized for two categories of potential effects: noncarcinogenic and carcinogenic. These two categories are selected because of the slightly differing methodologies for estimating potential health risks associated with exposures to carcinogens and noncarcinogens. The toxicity assessment section of this HHRA methodology discusses obtaining toxicity values, developing toxicity profiles (for those COCs not listed in IRIS or HEAST), and, if required, preparing a toxicity assessment TM.

6.1 Obtaining Toxicity Values

The toxicity values used quantitatively in HHRA are obtained from two major sources. The primary source of information is EPA's *Integrated Risk Information System* (IRIS) (EPA, 1994b). IRIS contains only those toxicity values that have been verified by EPA's Reference Dose or Carcinogen Risk Assessment Verification Endeavor (CRAVE) Work Groups. The IRIS database is updated monthly and, per RAGS, supersedes all other sources of toxicity information. If the necessary data are not available in IRIS, EPA's most recent issue of *Health Effects Assessment Summary Tables* (HEAST) (for example EPA, 1994c) is used. The tables are published annually and updated approximately two times per year with supplements. HEAST contains a comprehensive listing of provisional risk assessment information that has undergone review and has the concurrence of individual EPA Program Offices, but has not had enough review to be recognized as high-quality, agency-wide consensus information (EPA, 1993). HEAST is also the only source for radionuclide slope factors. Values that are pending or that have been withdrawn should not be used quantitatively unless an EPA Region VIII toxicologist approves their use for RFETS risk assessment. Route-to-route extrapolation of toxicity values is not recommended and historically has not been done at RFETS except were oral criteria is used for dermal exposures.

Secondary sources of information may be used qualitatively in HHRA. Previous years of IRIS and HEAST may be reviewed to track changing values. EPA toxicologists, both regional and national, may also serve as information sources and may provide contact to the Environmental Criteria and Assessment Office for provisional values. All information sources should be documented in the toxicity assessment.

6.1.1 Toxicity Assessment for Noncarcinogenic Effects

Potential noncarcinogenic effects will be evaluated in the risk characterization by comparing daily intakes (calculated in the exposure assessment) with chronic RfDs developed by EPA. This section provides a definition of an RfD and discusses how it will be applied in the risk assessment.

A chronic RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure that can be incurred during a lifetime, without an appreciable risk of a noncancer effect being incurred in human populations, including sensitive subgroups (EPA, 1989a). The RfD is based on the assumption that thresholds exist for noncarcinogenic toxic effects (e.g., liver or kidney damage). RfDs are typically calculated by dividing a dose (representing a no-observed-adverse-affect level or a lowest-observed-adverse-effect level), at which there are no significant measurable effects produced, by an uncertainty or safety factor that typically ranges from 10 to 10,000. The RfD is rounded to one significant figure and is presented in units of mg/kg-day. Thus, there should be no adverse effects associated with chronic daily intakes below the RfD value. Conversely, if chronic daily intakes exceed this threshold level, there is a potential that some adverse noncarcinogenic health effects might be observed in exposed individuals.

RfDs have been derived by EPA for both oral and inhalation exposures. However, in January 1991, EPA decided to replace inhalation RfDs with Reference Concentrations (RfCs). RfCs are expressed in terms of concentrations in air (mg/m^3), not in terms of "dose" (mg/kg-day). This decision was based on two factors: 1) EPA believed that it was technically more accurate to base toxicity values directly on measured air concentrations instead of making the

metabolic, pharmacokinetic, and/or other adjustments required to estimate an internal dose; and 2) for compounds that elicit route-of-entry effects (e.g., sensitizers and irritants), where the toxic effect is to the respiratory system or exchange boundary, EPA believed that a measure of internal dose might inappropriately imply effects to other organ systems or effects from other exposure routes (EPA, 1993).

The chronic oral and inhalation RfDs and RfCs for the COCs should be compiled in a table for the HHRA report. The table should also provide information on the uncertainty factors used to derive the RfDs, the overall confidence in the RfD (as provided in IRIS), and the target organs and critical effects that are the basis of the RfD. The table should also indicate how specific inhalation RfDs are derived, (e.g., through a route-to-route extrapolation from the oral RfD or through extrapolation from the RfC). An example of a table for presentation of noncarcinogenic toxicity values and supporting information is provided as Table 6-1.

6.1.2 Toxicity Assessment for Carcinogenic Effects

Potential carcinogenic risks will be expressed as an estimated probability that an individual might develop cancer from lifetime exposure. This probability is based on projected intakes and chemical-specific dose-response data called cancer slope factors (CSFs). CSFs and the estimated daily intake of a compound, averaged over a lifetime of exposure, are used to estimate the incremental risk that an individual exposed to that compound may develop cancer. There are two classes of potential carcinogens: chemical carcinogens and radionuclides. For the purposes of toxicity assessment, each of these two classes of elements or compounds are discussed separately.

6.1.2.1 Toxicity Assessment for Chemical Carcinogens – Evidence of chemical carcinogenicity originates primarily from two sources: lifetime studies with laboratory animals and human (epidemiological) studies. For most chemical carcinogens, animal data from laboratory experiments represent the primary basis for the extrapolation. Assumptions relevant to the following issues arise from extrapolating experimental results:

Table 6-1
Toxicity Constants for COCs
(for chronic noncarcinogenic effects)

COC	Oral RfD (mg/kg-day)	Inhalation RfC (mg/m^3)	Inhalation RfD (mg/kg-day)	Uncertainty Factor	Overall Confidence in RfD	Target Organ/ Critical Effect	Reference
COC 1	xxxxx	Pending	Pending	1,000	Medium	Liver/Heptatic Lesions	Most current applicable reference
COC 2	xxxxx	No Data	No Data	1,000	Medium	Liver/Heptatic Lesions	Most current applicable reference
COC N	Withdrawn	xxxxx	No Data	10	High	Liver/Heptatic Lesions	Most current applicable reference

- Across species (i.e., from laboratory animals to humans)
- From high-dose regions (i.e., levels to which laboratory animals are exposed) to low-dose regions (i.e, levels to which humans are likely to be exposed in the environment)
- Across routes of administration (e.g., inhalation versus ingestion).

Federal regulatory agencies have traditionally estimated human cancer risks associated with exposure to chemical carcinogens on the administered-dose basis according to the following approach:

- The relationship between the administered dose and the incidence of cancer in animals is based on laboratory animal bioassay results.
- The relationship between the administered dose and the incidence of cancer in the low-dose range is based on mathematical models.
- The dose-response relationship is assumed to be the same for both humans and animals if the administered dose is measured in the proper units.

Thus, effects from exposure to high (i.e., administered) doses are based on laboratory animal bioassay results, while effects associated with exposure to low doses of a chemical are generally estimated from mathematical models.

For chemical carcinogens, EPA assumes a small number of molecular events can evoke changes in a single cell that can lead to uncontrolled cellular proliferation and tumor induction. This mechanism for carcinogenesis is referred to as stochastic, which means that there is theoretically no level of exposure to a given chemical carcinogen that does not pose a small, but finite, probability of generating a carcinogenic response. Since risk at low exposure levels cannot be measured directly either in laboratory animals or human epidemiology studies, various mathematical models have been proposed to extrapolate from high to low doses (i.e., to estimate the dose-response relationship at low doses).

Currently, regulatory decisions are based on the output of the linearized multistage model (EPA, 1989a). The basis of the linearized multistage model is that multiple events may be

needed to yield tumor induction (Crump et al., 1977). The linearized multistage model reflects the biological variability in tumor frequencies observed in animal or human studies. The dose-response relationship predicted by this model at low doses is essentially linear. CSFs calculated for nonradiological carcinogens using the multistage model represent the 95% UCL on the probability of a carcinogenic response. Consequently, risk estimates based on these CSFs are conservative estimates representing upper-bound estimates of risk where there is only a 5-percent probability that the actual risk is greater than the estimated risk.

Uncertainties in the toxicity assessment for chemical carcinogens are dealt with by classifying each chemical into one of several groups, according to the weight-of-evidence from epidemiological studies and animal studies. These Groups are shown in Table 6-2.

Table 6-2
Carcinogen Groups

Weight-of-Evidence	Description
A	Human Carcinogen (sufficient evidence of carcinogenicity in humans)
B	Probable Human Carcinogen (B1-limited evidence of carcinogenicity in humans; B2-sufficient evidence of carcinogenicity in animals with inadequate or lack of evidence in humans)
C	Possible Human Carcinogen (limited evidence of carcinogenicity in animals and inadequate or lack of human data)
D	Not Classifiable as to Human Carcinogenicity (inadequate or no evidence)
E	Evidence of Noncarcinogenicity for Humans (no evidence of carcinogenicity in adequate studies)

The oral and inhalation CSFs for the COCs should be compiled in a table, including the weight-of-evidence, source reference, and date. In addition, as with RfDs, the CRAVE Work Group believes that a unit conversion is required to present inhalation CSFs in the units of $(mg/kg\text{-}day)^{-1}$. Consequently, CSFs should also be provided for the inhalation route as unit risks in units of "per microgram per cubic meter" $(\mu g/m^3)^{-1}$. An example of a table for carcinogenic toxicity values and supporting information is provided as Table 6-3.

Table 6-3

Toxicity Constants for COCs (for carcinogenic effects)

COC	CSF oral $(mg/kg\text{-}day)^{-1}$	CSF inh. $(\mu g/m^3)^{-1}$	CSF inh. $(mg/kg\text{-}day)^{-1}$	Weight of Evidence	Reference	Notes
Non-Radionuclides						
COC 1	xxxxx	xxxxx	xxxxx	A	Most current applicable reference	
COC 2	xxxxx	xxxxx	xxxxx	B2	Most current applicable reference	
COC n	Pending	Pending	Pending	—	Most current applicable reference	
Radionuclides						
	Oral CSF Risk/pCi	**Inhalation CSF Risk/pCi**		**Weight of Evidence**	**Reference**	**Notes**
COC 1	xxxxx	xxxxx		A	Most current applicable reference	
COC n	xxxxx	xxxxx		A	Most current applicable reference	

6.1.2.2 Toxicity Constants for Radionuclides - Extensive literature exists that describes the health effects of radionuclides on humans and animals. Intensive research by national and international commissions has established universally accepted limits to which workers and the public may be exposed without clinically detectable effects. This literature has resulted in EPA classifying all radionuclides as Group A carcinogens because they emit ionizing radiation, which, at high doses, has been associated with increased cancer incidence in humans. For radionuclides, human epidemiological data collected from the survivors of the Hiroshima and Nagasaki bomb attacks form the basis for the most recent extrapolation by the National Academy of Sciences (1980). Conversely, for most nonradiological carcinogens, animal data from laboratory studies provide the primary basis for the extrapolation. Another fundamental difference between the assessment of potential toxicity associated with exposure to radionuclide and nonradionuclide carcinogens is that CSFs for radionculides are typically best estimates (mean or median values rather than upper 95th percentile values. Furthermore, in the past, risk factors for radionuclides have generally been based on fatalities (i.e., the number of laboratory animals or people who actually died from cancer), while CSFs for nonradiological carcinogens are based on incidence (i.e., the number of lab animals or people who developed cancer). Finally, the CSFs for radionuclides are expressed in different units, i.e., risk per pCi $(pCi)^{-1}$ rather than $(mg/kg\text{-}day)^{-1}$.

Radionuclide CSFs may be included in the same table as chemical carcinogens, however they should be grouped separately due to the differences in units. Example Table 6-3 also provides an example presentation of radionuclide CSFs. The nonthreshold radionuclide CSFs account for:

- The amount of radionuclide transported into the bloodstream
- The decay of radioactive progeny within the body
- The distribution and retention of the radionuclide and its progeny (if any) in the body
- The radiation dose delivered to specific organs and tissues
- The age and sex of the exposed individuals (EPA, 1993).

6.2 Developing Toxicity Profiles

Consistent with agreements between DOE, EPA, and CDPHE, toxicity profiles will be developed only for COCs that do not have toxicity values in the current IRIS or HEAST. The profiles should be coordinated with EPA and CDPHE toxicologists prior to presentation in the HHRA report.

The profiles should be developed by a toxicologist to present general and contaminant-specific information on health effects relating to the HHRA COCs. General information should be provided on the class of chemical and its uses. Specific information should be presented on the effects reported in different studies, including exposure levels, biological endpoints, and dose-response. The strength of the studies should also be discussed, along with toxicity values and supporting information on how EPA derived them.

The following is an example toxicity profile for carbon tetrachloride, however, this example does not cite specific references.

> Carbon tetrachloride is an organic solvent which was, until recently, widely used as an industrial and household cleaning fluid. Recently, its household and industrial use has been severely restricted. Carbon tetrachloride, like chloroform, has anesthetic properties, which may lead to confusion and coma. Liver damage may result from either acute or chronic exposure. Fatty liver and centrilobular necrosis readily develop at low levels of chronic exposure, and in humans this is followed by kidney failure, which may be the ultimate cause of death.
>
> This compound has been more extensively studied regarding its toxic effects than any other aliphatic hydrocarbon. Carbon tetrachloride may cause damage to the heart, liver, kidneys, and the central nervous system (CNS) after high oral or inhalation exposures. At lower exposures, it may cause biochemical alterations (e.g., liquid peroxidation), nausea, and headaches. The chronic oral RfD for carbon tetrachloride is 7×10^{-4} mg/kg-day with an uncertainty factor of 1,000 (to account for interspecies and intrahuman variability). At the lowest observed adverse effect level, exposures to carbon tetrachloride produced liver lesions in rats. Although the principal study from which the RfD was derived was well done, and good dose-response data were available from a variety of other studies, confidence in the RfD was judged to be medium since supporting studies on possible reproductive and teratogenic effects are not available. An inhalation reference concentration is not available in IRIS.

The carcinogenicity of carbon tetrachloride, through both the inhalation and ingestion pathway, has been established with a variety of test animals and a number of gavage studies. Carbon tetrachloride has produced hepatocellular carcinomas in rats, mice, and hamsters. It is classified as a Group B2 carcinogen with an oral CSF of 0.13 $(mg/kg\text{-}day)^{-1}$. Since risk estimates generated from oral cancer studies varied by two orders of magnitude, EPA calculated the CSF using the geometric mean of the available data to account for deficiencies in several of the studies. The inhalation unit risk is 1.5×10^{-5} $(\mu g/m^3)^{-1}$ or 0.052 $(mg/kg\text{-}day)^{-1}$. The inhalation unit risk is based on the oral exposure data and assumes a 40% absorption rate by humans. Several studies of workers who may have used carbon tetrachloride have suggested that these individuals may have an excess cancer risk.

A toxicity profile should provide a complete description and should not necessarily be limited to the type and depth of information provided in this example. The depth of the toxicity profile should depend on the information available and the professional judgement of the toxicologist.

6.3 Preparing a Toxicity Assessment Technical Memorandum

According to the agreement between DOE, EPA, and CDPHE, the TM on toxicity assessment will contain only information on COCs that do not have toxicity information in IRIS or HEAST. If toxicity information is available in IRIS or HEAST for all COCs, no TM is required. If toxicity values have been derived, or when withdrawn or pending values are used, then a TM or letter report on toxicity assessment is required to present the appropriate information. For these COCs, the TM or letter report on toxicity assessment should include tables of COC toxicity values for noncarcinogenic and carcinogenic effects similar to example Tables 6-1 and 6-3. The toxicologist should include text with the tables explaining the derivation of the toxicity values along with toxicity profiles.

7.0 RISK CHARACTERIZATION

Risk characterization involves estimating the magnitude of the potential adverse effects of COCs under study and summarizing risks to public health. Risk characterization considers the nature and weight-of-evidence supporting these risk estimates and the magnitude of uncertainty surrounding those estimates. Risk characterization combines the results of the exposure and toxicity assessments to provide numerical estimates of health risk. These estimates are comparisons of exposure levels with RfDs or estimates of the lifetime cancer risk for a given intake. The process of characterizing risk includes the following:

- Calculating and characterizing cancer risk and noncarcinogenic effects
- Conducting qualitative uncertainty analysis
- Conducting quantitative uncertainty analysis.

7.1 Calculating and Characterizing Cancer Risk and Noncarcinogenic Effects

To quantify the health risks, the intakes are first calculated for each COC for each applicable scenario. The CT and RME intakes are calculated based on measured or modeled concentrations, and use the methodology documented in the RAGS (EPA, 1989a) and discussed in Section 5. The specific intakes are then compared to the applicable chemical-specific toxicological data, discussed in Section 6, to determine the CT and RME health risks.

The health risks from each potential contaminant are calculated to first determine potential carcinogenic effects and secondly to determine potential noncarcinogenic effects. Each of these calculations are discussed in the following sections.

7.1.1 Determining Carcinogenic Effects

The following calculations are used to determine carcinogenic effects by obtaining numerical estimates, (i.e., unitless probability) of lifetime cancer risks:

$$RISK = INTAKE \times CSF \quad (7.1)$$

where:

Risk	=	Potential lifetime excess cancer risk (unitless)
CSF	=	Slope factor, for chemicals $(mg/kg\text{-}day)^{-1}$, or $(pCi)^{-1}$
Intake	=	Chemical intake (mg/kg-day), or (pCi)

Inhalation and oral ingestion CSFs are used with respective inhalation and ingestion intakes to estimate risks. Chemical CSFs are estimated through the use of mathematical extrapolation models for estimating the largest possible linear slope at low extrapolated doses that is consistent with the data. Radionuclide slope factors are estimates derived from human epidemiological studies. The CSF is characterized as an upperbound estimate.

Cancer risks are summed separately across all potential chemical carcinogens and across all radionuclides considered in the risk assessment using the following equation:

$$RISK_T = \sum RISK_i \quad (7.2)$$

where:

$RISK_T$	=	Total cancer risk, expressed as a unitless probability
$RISK_i$	=	Risk estimate for the i^{th} contaminant

This equation is an approximation of the precise equation for combining risks to account for the probability of the same individual developing cancer as a consequence of exposure to two or more carcinogens. As stated in RAGS (EPA, 1989a), the difference between the precise equation and this approximation is negligible for total cancer risks less than 0.1. This risk summation assumes independence of action by the compounds involved. Some limitations are posed by using this approach, and they are discussed in RAGS (EPA, 1989a). For example, limitations apply when adding potential carcinogenic risk across the pertinent weight-of-evidence cancer classes.

The software used to calculate the carcinogenic risks may be configured to print a table of risks for each scenario. Each table can show contaminant and pathway-specific risk if contaminants are presented in rows and pathways are presented by column. After reasonable exposure pathway combinations are identified, the likelihood that the same individuals would consistently be exposed by more than one pathway is evaluated. In most situations a receptor could be exposed by several pathways in combination. For these situations, risks may be subtotaled across pathways for each contaminant.

A total carcinogenic risk may be summed across weight-of-evidence classifications as an additional point of reference. In accordance with EPA guidance, only one significant digit is retained when summarizing calculated risks (EPA, 1989a). Table 7-1 provides an example table shell to document carcinogenic risks.

The HHRA text should reference each table and discuss risks that exceed the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) risk range of 10^{-4} to 10^{-6} (EPA, 1990). Specifically, the pathways and contaminants driving the risk, should be noted and accompanied by any necessary qualifying statements. The text should not repeat the entire table, but should summarize more notable results.

In addition to presenting the incremental cancer risks due to contaminants at the site, perspective may be provided by giving examples of typical background sources of risk such as arsenic or radon and progeny. Because the public is often unaware of the numerous conservative assumptions involved in an HHRA, the text should note the assumptions associated with the calculations and reference the reader to the uncertainty section.

A summary table presenting risk subtotals for all scenarios should also be created for the HHRA risk summary section. This table may be presented by placing the results for each scenario in rows, and allowing weight-of-evidence Group A, B, and C subtotals in the columns.

Table 7-1
RME Carcinogenic Risk

Chemical	Pathway 1	Pathway 2	Pathway 3	Pathway n	Total
COC 1					
COC 2					
COC 3					
COC n					
	Pathway 1 Total	**Pathway 2 Total**	**Pathway 3 Total**	**Pathway n Total**	
					Total Risk

7.1.2 Determining Noncarcinogenic Effects

Health risks associated with exposure to individual noncarcinogenic compounds are determined by calculating hazard quotients (HQs) and hazard indices (HIs). The noncarcinogen HQ is the ratio of the intake or exposure level to the RfD, as follows:

$$HQ = INTAKE/RfD \tag{7.3}$$

where:

HQ	=	Noncarcinogen hazard quotient
Intake	=	Chemical intake (mg/kg-day)
RfD	=	Reference dose (mg/kg-day)

Chronic RfDs are extracted from IRIS and HEAST. Similar to CSFs, RfDs for inhalation and oral ingestion are used for inhalation and oral intakes, respectively.

HIs are the summed hazard quotients for each chemical across the exposure pathways. If the HI for any chemical exceeds unity, there may be concern for potential health effects. The HI is calculated using the following equation:

$$HI = \sum \frac{E_i}{RfD_i} \tag{7.4}$$

where:

HI = Hazard index
E_i = Exposure level (intake) for the i^{th} toxicant
RfD_i = Reference dose for the i^{th} toxicant

E and RfD are expressed in the same units and represent the same exposure period.

These HI values should not be interpreted as statistical probabilities of an effect occurring, however, if the HI exceeds unity there may be a concern for potential noncancer effects. In

general, the greater the HI above unity, the greater the level of concern. However, the level of concern does not increase linearly as the HI approaches or exceeds unity. Further discussions and limitations on the application of this procedure are contained in RAGS (EPA, 1989a).

Noncarcinogenic effects are presented in the HHRA text and tables similar to those used in the presentation of carcinogenic risk. Each table can show contaminant and pathway-specific effects if contaminants are presented in rows and pathways are presented by column. After reasonable exposure pathway combinations are identified, the likelihood that the same individuals would consistently be exposed to more than one pathway is evaluated. In most situations, a receptor could be exposed by several pathways in combination. For these situations, HQs may be subtotaled across pathways for each contaminant.

HQs approaching or exceeding one may be summed according to target organ to calculate the total HI by target organ. For a specific receptor scenario, a total HI may also be summed across all pathways and contaminants as an additional point of reference, but is subject to limitations. As is the convention with carcinogenic risk, only one significant digit is retained when summarizing calculated effects (EPA, 1989a). Table 7-2 provides an example table shell for presentation of HIs.

The HHRA text should reference each table and discuss hazard quotients that exceed unity. Specifically, the pathways and contaminants driving the risk should be noted and accompanied by any necessary qualifying statements. The HHRA text should not repeat the entire table, but should summarize more notable results.

A summary table presenting HI subtotals for all scenarios should also be created for presentation in the HHRA risk summary section. This may be presented by placing the results for each scenario in rows, and providing information on hazard indices, dominant COC, and dominant pathway in columns.

Table 7-2
RME Noncarcinogenic HI

Chemical	Pathway 1	Pathway 2	Pathway 3	Pathway n	Total
Contaminant 1					
Contaminant 2					
Contaminant 3					
Contaminant n					
	Pathway 1 Total	Pathway 2 Total	Pathway 3 Total	Pathway n Total	
					Total HI

7.2 Conducting Qualitative Uncertainty Analysis

The quantification of uncertainty is an important component of the risk assessment process. According to the EPA *Guidance on Risk Characterization for Risk Managers and Risk Assessors* (EPA, 1992c), point estimates of risk "do not fully convey the range of information considered and used in developing the assessment." To provide information about the uncertainties associated with the RME estimate, uncertainties are identified during the HHRA process and are presented in qualitative and, where appropriate, quantitative terms.

There are four stages of analysis applied in the risk assessment process that can introduce uncertainties:

- Data Collection and Evaluation
- Exposure Assessment
- Toxicity Assessment
- Risk Characterization.

The uncertainty analysis characterizes the various sources and their contributions to uncertainty in the HHRA. These uncertainties are driven by uncertainty in the site investigation data, the likelihood of hypothetical exposure scenarios, the transport models used to estimate concentrations at receptor locations, receptor intake parameters, and the toxicity values used to characterize risk. Additionally, uncertainties are introduced in the risk assessment when exposures to several substances across multiple pathways are summed.

The concept of uncertainty can be more fully defined by distinguishing between variability and knowledge uncertainty. Variable parameters are those that reflect heterogeneity in a well-characterized population, for which the distributions would not generally be narrowed through further measurement or study. Uncertain parameters reflect a lack of information about properties that are invariant and whose single, true value could be known exactly by the use of a perfect measuring device. Where appropriate, qualitative uncertainty analysis may distinguish between variability and uncertainty.

Qualitative uncertainty analysis should identify each key source of uncertainty, present an estimate of the relative impact of the uncertainty on the HHRA, and include any clarifying remarks. For many of the contributors, presenting uncertainty in a tabular format is sufficient. Table 7-3 provides an example format for summarizing the uncertainties and limitations in an HHRA. For sources of uncertainty requiring more discussion than is convenient in a table, additional clarification may be provided in accompanying text.

7.3 Conducting Quantitative Uncertainty Analysis

In some cases, quantitative uncertainty analysis may be conducted in addition to the qualitative uncertainty analysis. Quantitative uncertainty analysis should be performed on chemicals and/or sets of chemicals that have a carcinogenic risk greater than 1×10^{-4} or a noncarcinogenic HQ or HI greater than 1. To quantify the uncertainty in the final risk characterization estimates, Monte Carlo simulations may be used for the pathways dominating the risk.

The Monte Carlo simulation is a technique that can be used to provide a probability function of estimated risk using random values of exposure factors and toxicity values in an exposure scenario. A Monte Carlo simulation involves assigning a joint probability distribution to the input variables (i.e., exposure factors) of an exposure scenario. Next, a large number of independent samples from the assigned joint distribution are taken and the corresponding outputs calculated. This is accomplished by repeated computer iterations using random numbers to assign values to the exposure factors. The simulated output represents a sample from the true output distribution. Methods of statistical inference are used to estimate, from the output sample, key parameters of the output distribution (e.g., percentiles).

The risk distributions produced by Monte Carlo simulations present significantly more information than do point estimates. However, the level of effort involved in conducting a quantitative uncertainty analysis should be weighed against the importance of this information to risk managers.

Table 7-3
Human Health Risk Assessment Uncertainty Factors

Uncertainty Factor	Effect of Uncertainty	Comment
Sampling and Analysis		
Use of invalidated data	May slightly underestimate risk	
Identification of OU contaminants	May slightly over-or underestimate risk	
Detection limits/COC screening	May slightly over-or underestimate risk	
Concentration-toxicity screen	May slightly over-or underestimate risk	
Data set completeness	May slightly over-or underestimate risk	
Fate and Transport Estimation		
Soil-gas source term assumptions	May over-or underestimate risk	
Natural infiltration rate	May overestimate risk	
Moisture content	May over-or underestimate risk	
Water table fluctuations	May slightly over-or underestimate risk	
Effect of micrometeorology on air dispersion	May slightly over-or under estimate risk	
Variability in annual meteorological data	May slightly over-or under estimate risk	
Plant uptake estimation	May slightly under-or over estimate risk	
Exposure Estimation		
Exposure scenario assumptions	May overestimate risk	
Exposure parameter assumptions	May overestimate risk	
Receptor locations	May overestimate risk	
Exposure duration	May over-or underestimate risk	
Non chemical-specific constants (not dependent on chemical properties)	May overestimate risk	

Table 7-3
(continued)

Uncertainty Factor	Effect of Uncertainty	Comment
Exposure Estimation (continued)		
Exclusion of some hypothetical pathways from the exposure scenarios	May underestimate risk	
External radiation	May slightly underestimate risk	
Permeability coefficients	May slightly over-or underestimate risk	
Plant ingestion rate	May slightly over-or underestimate risk	
Model does not consider biotic decay	May overestimate risk	
Exclusion of transformation products	May underestimate risk	
Toxicological data		
Use of cancer slope factors	May overestimate risk	
Critical toxicity values derived primarily from animal studies	May over-or underestimate risk	
Critical toxicity values derived primarily from high doses, most exposures are at low doses	May over-or underestimate risk	
Critical toxicity values and classification of carcinogens	May over-or underestimate risk	
Lack of inhalation slope factors	May underestimate risk	
Use of oral slope factors to evaluate dermal absorption	May over-or underestimate risk	
Addition of risks across weight-of-evidence classifications	May overestimate risk	
Lack of RfDs or RfCs	May underestimate risk	
Lack of dermal absorption or direct action toxicity values	May slightly underestimate risk	

8.0 SUGGESTED HHRA REPORT ORGANIZATION

After the four TMs and the CDPHE letter report are submitted, and after the risk calculations are completed, the HHRA report is written. HHRA reports are generally written as "stand alone" documents for RFETS and are written for members of the public with a college education. The reports typically contain the following sections:

Section 1.0 Introduction
Section 2.0 Site Description
Section 3.0 COC Identification
Section 4.0 Scenario and Pathway Identification
Section 5.0 Exposure Assessment
Section 6.0 Toxicity Assessment
Section 7.0 Risk Characterization
Section 8.0 Summary
Section 9. References
Appendices.

The following subsections describe the contents of each section of an HHRA report. These subsections discuss only minimum information for the HHRA, additional information can be included that would better describe the methodologies, approaches, and results to the reader.

8.1 Section 1.0 Introduction

Section 1.0 Introduction, of the HHRA should provide the HHRA's purpose, scope, objectives, and the report organization. IAG requirements should be discussed in the Introduction. The Introduction can also include a chronology of the previous investigations.

8.2 Section 2.0 Site Description

Section 2.0 Site Description, presents a brief summary of the presentations and findings of the RI report that include a description of IHSSs, meteorology and climate, hydrogeology, flora and fauna, demographics and local land use, determination of contaminants, nature and extent of contamination, and contaminant migration pathways. Tables, figures, and maps can be used

to summarize contaminants and media at the site, general and specific site areas and locations, and contaminant detection locations. The reader of the HHRA report can be referred to the source documents (e.g., RFI/RI report sections) for further detail.

8.3 Section 3.0 COC Identification

Section 3.0 COC Identification, presents the methodology and its application in the identification and selection of COCs. A background comparison is presented that discusses applicable statistical tests and resulting potential COCs. If lengthy, this background comparison may be presented as an attachment. The COC screening methodology is presented and applied to derive a list of COCs to be used in the remainder of the risk assessment. Tables 3-1 through 3-4 provide examples of: summary statistics, the concentration-toxicity screen, the resulting COCs, and the COC screening process.

8.4 Section 4.0 Scenario and Pathway Identification

Section 4.0 Scenario of Pathway Identification, discusses potential scenarios and pathways applicable to the existing and potential land use. A discussion is provided for each current and potential on-site and off-site land use. Potential receptors that could be exposed to COCs in the context of land uses discussed in Section 2 of the HHRA are then presented. Finally, justification of the selection of exposure pathways according to the CSM is provided.

8.5 Section 5.0 Exposure Assessment

Section 5.0 Exposure Assessment, first presents pathway-specific information such as intake equations and modeling data, followed by information that is both scenario-specific and pathway-specific such as exposure parameters and exposure concentrations. Where modeling was used to provide the exposure concentrations, a brief summary of the model is provided. Finally, the results calculated are presented for each scenario. Tables and figures can include model applications, chemical-specific constants, intake equations and parameters, and resulting receptor intakes. Tables 5-1 and 5-2 in this HHRA methodology provide some presentation examples.

8.6 Section 6.0 Toxicity Assessment

Section 6.0 Toxicity Assessment, provides COC toxicity information including carcinogenic and noncarcinogenic effects. Tables are used to summarize toxicity values for each COC, with toxicity profiles were applicably presented as text. Tables 6-1 through 6-3 in this HHRA methodology provide examples of summary toxicity information.

8.7 Section 7.0 Risk Characterization

Section 7.0 Risk Characterization, presents the methodology and results of combining the results of the exposure and toxicity assessments. These results provide numerical estimates of potential health risk. Considered in the approach are the nature and weight-of-evidence supporting the risk estimates and the magnitude of uncertainty. Tables and figures include presentations of specific and summarized carcinogenic risk and noncarcinogenic HIs, summaries of sources of uncertainty, and the potential impact on the assessment. Tables 7-1 through 7-3 of this HHRA methodology provide examples of these risk characterization calculations and observations, and qualitative uncertainty analysis.

8.8 Section 8.0 Summary

Section 8.0 Summary, summarizes the methodology implemented for the HHRA and the overall results. Text, tables, and figures should summarize the entire HHRA into one section.

Section 8.0 can be written to be used for the HHRA portion of Section 6 of the RI/RFI Report. This section of the RFI/RI Report presents the BRA, which is comprised of the HHRA and the ERA. In addition, portions of the summary of the HHRA can be used for the executive summary of the RFI/RI Report. Section 8.0 may include summary tables of risk and discussion of risk drivers and associated uncertainties.

8.9 Section 9.0 References

Section 9.0 References, includes all references used throughout the HHRA.

8.10 Appendices

Appendices include additional information that would be helpful to the reader about the background, assumptions, or approach to any aspect of the HHRA. The following items briefly describe suggested contents for appendices to the HHRA. Additional appendices can be added.

- **Background Comparison** – This appendix discusses the background analysis process and results. Using statistical analysis, inorganic chemicals or radionuclides that are at or below background levels are eliminated from further consideration. Specific criterion for the background analysis is that none of the statistical tests indicate a statistically significant difference between background and site-specific populations.

- **Fate and Transport Model Descriptions and Applications** – This appendix provides a detailed description of the models used in the HHRA including methodologies and assumptions. Applications of each model are described and discussed. Examples of models include groundwater modeling, soil-gas modeling, and atmospheric modeling.

- **Calculating of 95% UCLs for COCs** – This appendix provides a brief description of the methodologies and assumptions used to determine the 95% UCLs for the COCs. It can also include tables to summarize the results of the calculations for each COC.

9.0 REFERENCES

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APPENDIX A

DATA CLEAN-UP AND TREATMENT GUIDELINES

APPENDIX A
DATA CLEAN UP AND TREATMENT GUIDELINES

This appendix for data clean up and treatment guidelines contains an example that was taken directly from a recent RFETS COCTM. The example is the appendix A, Data Preparation, from the OU3 COCTM. There are four attachments and their respective appendices that are contained in the OU3 appendix but to conserve space are not included in this example.

APPENDIX A. DATA PREPARATION

A-1.0 INTRODUCTION

The OU 3 database was developed to store and organize the data from environmental sampling programs at the RFETS and surrounding area that were used to prepare the RCRA Facility Investigation/Remedial Investigation (RFI/RI), including the Human Health Risk Assessment and the Environmental Evaluation, for OU 3. The OU 3 database is composed of data from the following sources:

- Rocky Flats Environmental Database System (RFEDS)
- 1983/84 Sediment Sampling Investigations data (DOE, 1991)
- Rock Creek Background Soil Samples (DOE, 1993a)
- Jefferson County Sampling Area Soil Samples (received from RFEDS)
- Background Geochemical Characterization Report (DOE, 1993b)
- Benchmark – Survey Data for Sample Points and Polygons

These sources provided the data sets in various formats; therefore, different procedures were used, depending on the data source, to prepare the data for use in the OU 3 database. This appendix describes the procedures followed for each data set.

The OU 3 database is managed according to the Data Management Plan (DOE, 1993c) developed for the OU 3 RFI/RI. The Data Management Plan describes in detail the data management system for the project and includes procedures for data management staff, computer hardware and software, data models and organization, data management, and data users.

The remainder of Appendix A describes the overall structure of the OU 3 database, data preparation steps, and quality control (QC) checks that were performed to generate the tables for the OU 3 database. Appendix A is organized into the following sections:

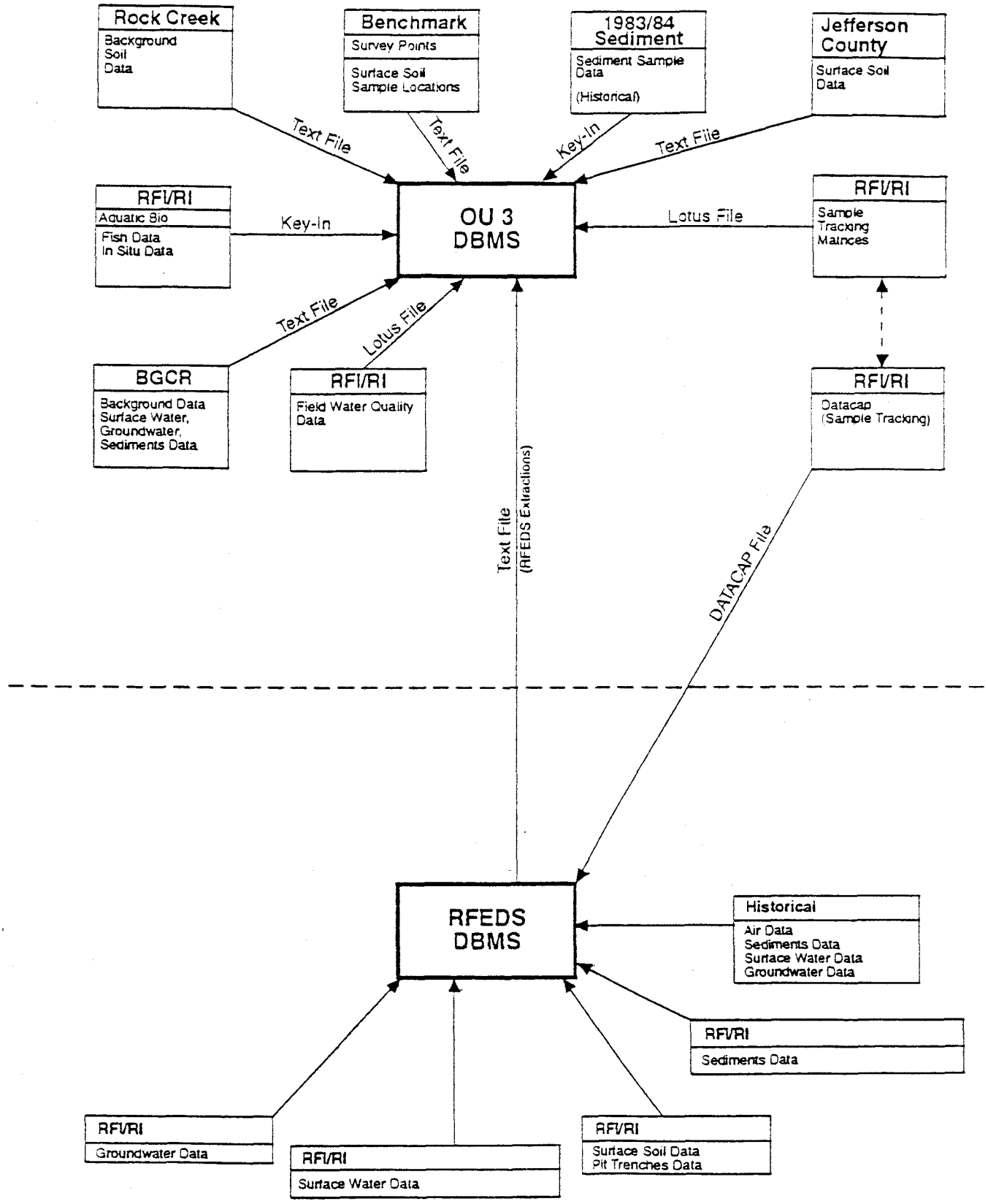
- OU 3 Database Structure
- RFEDS Data Preparation
- Additional Data Input
- Data Analysis Table
- Quality Control Checks

A-2.0 OU 3 DATABASE STRUCTURE

The database management system uses a relational data model, where the data accessed by users are contained in a number of separate tables, but are related through one or more key fields. Tables were created for data sets from each of the sources listed above. Additionally, a Data Evaluation table was created to statistically compare OU 3 data and background data and to calculate summary statistics and risk estimates. The Data Evaluation table contains fields that reflect the application of data-evaluation protocols specified by EG&G (EG&G, 1994).

The OU 3 database was designed as a set of independent Paradox (DOS Version 4.0 RDMS) tables containing fields of data. These tables can be linked through key fields (i.e., selected fields that are common to two or more tables). Figure A-1 presents an organization diagram of the OU 3 database. Table A-1 summarizes the OU 3 database structure and describes the contents of each Paradox table. Figure A-2 lists the fields contained in each table and shows relationships between the tables. Table A-2 contains definitions of the various fields.

In addition to the Paradox tables, OU 3 data are contained in ARC/INFO files to be used for producing Geographical Information System (GIS) plots of analytical results and sample locations. Analytical result and sample location data were transferred to ARC/INFO using ASCII comma-separated files.



RFEDS = Rocky Flats Environmental Database System
RFI/RI = RCRA Facility Investigation/Remedial Investigation

——— Direct relationship

- - - Indirect Relationship

BGCR = Background Geochemical Characterization Report (DOE, 1993c)
DBMS = Database Management System

Figure A-1
OU 3 DATABASE ORGANIZATION

TABLE A-1

OU 3 DATABASE STRUCTURE

Paradox Table Name	Paradox Table Description
DA{date}.db	Data for the statistical background comparison tests and other data analysis tasks. Contains original sample data from tables DT012694, JT012694, NB012694 (excluding outliers as identified in the BGCR), and OT012694. Surface soil sampling results (CDPHE and MHM methods) are averaged for each location. Contains fields that reflect EG&G data analysis protocols for nondetects. Rejected data (Validation = R) and QC data are not included.
DG{date}.db	Sample locations (OU 3 and background) and data grouping information.
DB{date}.db	Original and QC data from RFEDS.
DT{date}.db	Original data only from RFEDS.
DQ{date}.db	QC data only from RFEDS.
JS{date}.db	Jefferson County Sampling Area surface soil data (original and QC data).
JT{date}.db	Jefferson County Sampling Area surface soil data (original data only).
JQ{date}.db	Jefferson County Sampling Area surface soil data (QC data only).
NB{date}.db	BGCR data for selected sample locations (non-seep sediment and surface water locations; weathered claystone monitoring well locations – original data only). Outliers, as identified in the BGCR, are included.
O1{date}.db	Rock Creek Background Soil data from OU 1 RI Report (original and QC data).
OT{date}.db	Rock Creek Background Soil data from OU 1 RI Report (original data only).
OQ{date}.db	Rock Creek Background Soil data from OU 1 RI Report (QC data only).

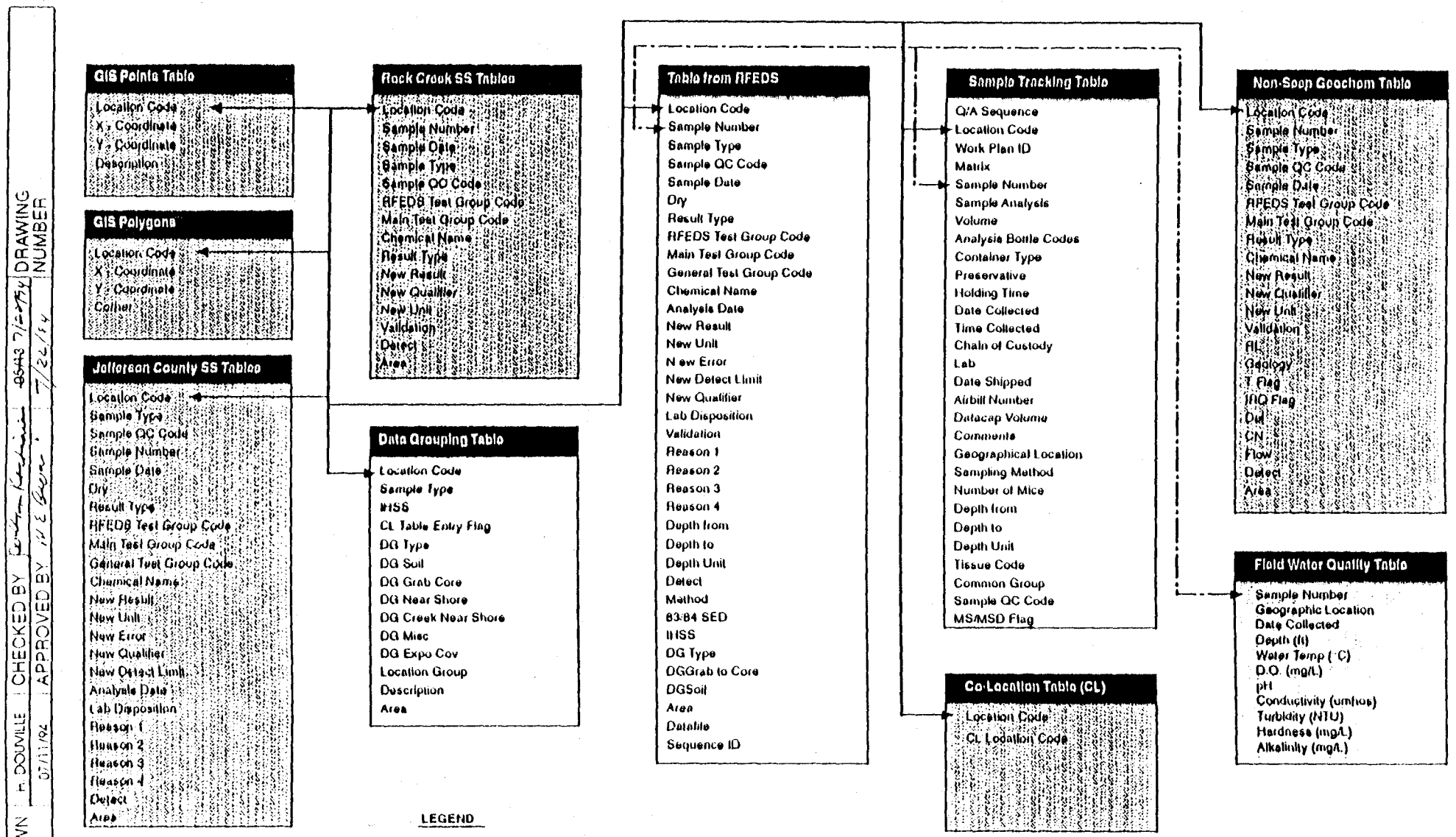
TABLE A-1

OU 3 DATABASE STRUCTURE

Paradox Table Name	Paradox Table Description
ST{date}.db	Sample tracking information.
FW{date}.db	Field water quality data associated with BIO samples.
CL{date}.db	Matrix of co-located samples (e.g., co-located BIO, SW, and SED samples).

Note:

{date} = Each Paradox table filename includes the date on which the table was created and/or modified. Therefore, the most current tables were clearly identified and used for data manipulations. For example, Paradox file DA081094.db was modified on August 10, 1994.



DRAWN BY n. DOUVILLE | CHECKED BY [illegible] 8643 7/27/94 | APPROVED BY [illegible] 7/22/94 | DRAWING NUMBER

BCGR = Background Geochemical Characterization Report (DOE, 1994)

Figure A-2
OU 3 DATABASE TABLE
RELATIONSHIP DIAGRAM

TABLE A-2

OU 3 DATABASE FIELD NAME DEFINITIONS

Field Name	Definition
DA Table	
LOCATION CODE	Indicates environmental medium/physical location; can be more than one **LOCATIONCODE** at the same physical location. Example: BI100092 <– Biology Location SD100092 <– Sediment Location SW100092 <– Surface Water Location are all at the same physical location.
SAMPLE TYPE	Designates environmental sample medium.
SAMPLE QC CODE	Codes a record as a REAL (i.e., original sample) or QC sample (e.g., DUP, FB).
SAMPLE NUMBER	Unique code designating a single sample taken at a **LOCATIONCODE** position; can be more than one sample number for a **LOCATIONCODE**.
SAMPLE DATE	Date sample was collected.
DRY	Denotes if sediment sample was dry at the time of collection.
RESULT TYPE	Codes a record as an original sample result (i.e., TRG = target) or a lab QC record (e.g., REP).
RFEDS TEST GROUP CODE	General chemical group code supplied by RFEDS; can be more than one **RFEDS TEST GROUP CODE** for an analytical method.
MAIN TEST GROUP CODE	Chemical group code; one code per analytical method.
GENERAL TEST GROUP CODE	General test that was performed on the sample.
CHEMICAL NAME	Analyte name.
ANALYSIS DATE	Date chemical analysis was performed.
NEW RESULT	Analytical result; validated result if available.

TABLE A-2

OU 3 DATABASE FIELD NAME DEFINITIONS

Field Name	Definition
ADJ RESULT	Adjusted result = One-half of the RESULT FIELD value (for nondetects only).
NEW UNIT	Unit associated with the result value.
NEW ERROR	Error term associated with radionuclide results.
NEW DETECT LIMIT	Detection limit (Detection limit = Instrument detection limit for OU 3 metals data Detection limit = Instrument detection limit or CRDL for BGCR metals data)
NEW QUALIFIER	Includes the qualifiers assigned by the laboratories and the data validators.
LAB DISPOSITION	If analytical results could not be transmitted, a reason disposition code is indicated.
VALIDATION	Validation codes assigned by the data validators. If the field is blank, the record has not been validated.
REASON1, REASON2, REASON3, REASON4	Explanation for validation codes.
DEPTH FROM	Upper boundary of a sediment core or pit trench segment.
DEPTH TO	Lower boundary of a sediment core or pit trench segment.
DEPTH UNIT	Unit for sediment core or pit trench segments.

TABLE A-2

OU 3 DATABASE FIELD NAME DEFINITIONS

Field Name	Definition
DETECT	The detect field marks records that contain a 'U' in the NEW QUALIFIER field as a nondetect. Example: NEWQUALIFIER Detect UJ——————>U J——————>BLANK UU——————>U •——————>BLANK B——————>BLANK UJ——————>U
ADJ DETECT	Adjusted detect: Reflects application of EG&G data analysis protocols. All radionuclides are designated as detects (i.e., ADJ DETECT field is BLANK); all B-qualified metals and water quality records are designated as detects. All other records with a "U" in the DETECT field are designated as nondetects (i.e., ADJ DETECT field contains a "U").
METHOD	Method used to collect a surface soil sample (CDH or MHM).
84/85 SED FLAG	Flags a record as belonging to the 1984/85 Sediment Sampling Investigations data set.
IHSS	Individual Hazardous Substance Site number
DGTYPE	Data grouping designation (e.g., CREEK, LAKE, PLOT, TRENCH).
DGGRABCORE	Data grouping designation for sediment samples indicating if GRAB or CORE sample.
DGSOIL	Data grouping designation for surface soil samples indicating if sample was located in the Remedy Acreage area.
AREA	Denotes if the record is background (B) or OU 3 site (S) data.

TABLE A-2

OU 3 DATABASE FIELD NAME DEFINITIONS

Field Name	Definition
Additional Fields - DG Table	
CL TABLE ENTRY	Indicates if additional information for the record is available in the Co-Located Sample table.
DGNEARSHORE	Data grouping designation for sediment samples.
DGCREEKNEARSHORE	Data grouping designation for sediment samples.
DGMISC	Miscellaneous data grouping designation – empty field
DGEXPOCOV	Data grouping designation for sediment sample locations – exposed vs. covered with water.
GISID	I.D. code from ARC/INFO GIS data files.
GISSAMPLELOCATION	GIS map location.
LOCATIONGROUP	General geographic location group.
DESCRIPTION	Description of sample location based on medium and geographic location.

A-3.0 RFEDS DATA PREPARATION

EG&G maintains the RFEDS. The majority of data records in the OU 3 database were extracted by EG&G from RFEDS as ASCII text fixed-field files. EG&G began with an initial extraction of data from RFEDS on December 17, 1992, and throughout the duration of the project added periodic RFEDS extractions containing updated and additional records. The final extraction of RFEDS data for the Draft RFI/RI report was on February 15, 1994. All extractions, including those prior to February 15, 1994 (i.e., December 17, 1992; January 20, 1993; February 10, 1993; March 17, 1993; April 1, 1993; May 5, 1993; June 10, 1993; September 16, 1993; November 16, 1993), were imported from the text files into Paradox on February 16, 1994 to create the OU 3 database for the Draft RFI/RI report.

The steps necessary to import and prepare RFEDS data for the OU 3 database are described in detail below.

1. Convert RFEDS data-extraction files to ASCII separated/delimited format.

2. Import the extraction into Paradox.

3. Correct database inconsistencies and separate data that will not be used in quantitative data-analysis tasks.

4. Identify and resolve redundant data records.

5. Assemble the main cleaned-up table (without resolved problem records).

6. Produce potential problem records report.

7. Review potential problem records report and select records to be added back to the main table.

8. Add selected record(s) from the review process back to the main table.

9. Copy main table to OU 3 database directory for RFETS.

10. Notify persons using OU 3 database of updated main table.

Note: In the description of preparation steps below, names of database fields are shown in all uppercase bold letters (e.g., **CHEMICAL NAME**, **MAIN TEST GROUP CODE**, and **NEW RESULT**).

STEP 1 – Convert RFEDS data-extraction files to ASCII separated/delimited format.

The RFEDS data extraction format is ASCII column-delimited (i.e., text files that consist of fields that are of a fixed length). Because Paradox cannot import column-delimited ASCII files, the column-delimited RFEDS data files are converted to ASCII separated/delimited (DAT) files using a general-purpose conversion program written in PASCAL. ASCII separated/delimited files are text files that consist of fields separated by a special character, usually a comma. Additionally, the alpha fields are delimited with a special character (i.e., quotation marks for these data). Alpha fields are delimited with a special delimiter character so those fields can contain the special separator character as part of the alpha string (e.g., chemical names that contain commas).

STEP 2 – Import the extraction into Paradox.

Using a custom script called IMPORTEX.SC, the DAT files are imported into Paradox. The imported data from the initial RFEDS extraction are put into a temporary table. The temporary table is then restructured to match the structure of the main raw data table, and the **SEQUENCE ID** field is used to link the temporary and main raw data tables. The temporary table records are then added to the main raw database table. The process is repeated for each extraction. Records from the source table (i.e., temporary table with RFEDS data) replace records in the destination table (i.e., main raw data table) if the **SEQUENCE ID** in the source table record already exists in the destination table. If the records from the source table are not

in the destination table, then the records from the source table are added to the destination table.

STEP 3 – Correct database inconsistencies and separate data that will not be used in quantitative data-analysis tasks.

Using a script named XCLEANUP.SC, the data are preprocessed to correct any inconsistencies found in the RFEDS data, such as the following:

- CHEMICAL NAME inconsistencies
- RFEDS TEST GROUP CODE name inconsistencies
- Obsolete RFEDS TEST GROUP CODE names
- Unit inconsistencies
- Multiple fields of analytical data for one record (i.e., data received from RFEDS contain fields for laboratory results and corrected results from the data-validation subcontractor; some records contain both laboratory and corrected results).

Additionally, the preprocessing step accomplishes the following:

- Separation of historical data (i.e, pre-1992 data that tend to have QC problems) from OU 3 sampling program data; historical data will be used qualitatively in the RFI/RI report.

- Separation of QC data from original sample data; QC data will be used in the RFI/RI report to evaluate quality of the data; only original data will be used for all other quantitative data-analysis tasks.

- Removal of data for any samples not associated with the OU 3 field investigation.

XCLEANUP.SC performs the following operations:

Separation of Historical Data

Historical data are identified by the following Location Codes:

SW001 through SW004
SED001 through SED004
GS001 through GS004

These data are removed from the main raw-data table and placed into a separate table for use in the RFI/RI report.

Separation of QC Data

QC data are identified using the **SAMPLE QC CODE** field:

Any samples with codes in the **SAMPLE QC CODE** field other than REAL, BLANK, or UNK (i.e, unknown) are considered to be QC samples.

QC data are also identified using the **RESULT TYPE** field:

Any samples with codes in the **RESULT TYPE** field other than TRG, DIL, BLANK, or UNK are considered to be QC samples.

Data identified as QC samples are removed from the main raw data table and placed into a temporary table for further processing.

Separation of Non-OU 3 Field Investigation Data:

OU 3 field investigation data are identified by the following suffixes in entries in the **SAMPLE NUMBER** field:

- CH
- WCU3 or WC

Records with suffixes in the **SAMPLE NUMBER** field other than those listed above are not included in the OU 3 database.

Inconsistencies in Analyte Names

Inconsistencies in analyte names (i.e., multiple names for the same chemical) found in the RFEDS data are corrected so that each chemical is listed by only one name in the OU 3 database (see Table A-3).

Obsolete RFEDS TEST GROUP CODES

Obsolete codes in the **RFEDS TEST GROUP CODE** field consist of the following:

- PDMETCLP
- PDMETNOCLP

Any records with the codes listed above in the **RFEDS TEST GROUP CODE** field are removed from the main raw data table. RFEDS replaces these codes with new codes. Therefore, if records with test group codes of PDMETCLP and PDMETNOCLP are left in the table, they represent duplicate records.

TABLE A-3

CHEMICAL NAME INCONSISTENCIES

Multiple Chemical Names	Changed to
RADIONUCLIDES	
GROSS ALPHA - DISSOLVED GROSS ALPHA - SUSPENDED GROSS ALPHA PARTICLE ACTIVITY	GROSS ALPHA
GROSS BETA - DISSOLVED GROSS BETA - SUSPENDED GROSS BETA PARTICLE ACTIVITY	GROSS BETA
PLUTONIUM 239 PLUTONIUM 239/240	PLUTONIUM 239/240
URANIUM 233, 234 URANIUM 234	URANIUM 233/234
WATER QUALITY	
CYANIDE CYANIDE, AMENABLE CYANIDES (SOLUBLE SALTS...)	CYANIDE
HEXAVALENT CHROMIUM CHROMIUM VI	HEXAVALENT CHROMIUM
NITRATE/NITRITE NITRATE/NITRITE (HISTORICAL...)	NITRATE/NITRITE
ORTHOPHOSPHATE PARATHION, ETHYL (INCORRECT CAS NUMBER CAUSED THIS TO BE LABELED INCORRECTLY - VERIFIED BY BETH MONTANO/EG&G)	ORTHOPHOSPHATE
SOLIDS, NONVOLATILE SUSPENDED TOTAL DISSOLVED SOLIDS	TOTAL DISSOLVED SOLIDS
TOTAL SOLIDS TOTAL SUSPENDED SOLIDS	TOTAL SUSPENDED SOLIDS
BICARBONATE BICARBONATE AS CACO3*	BICARBONATE AS CACO3

TABLE A-3

CHEMICAL NAME INCONSISTENCIES

Multiple Chemical Names	Changed to
CARBONATE CARBONATE AS CACO3	CARBONATE AS CACO3
ALKALINITY AS CACO3 TOTAL ALKALINITY	ALKALINITY AS CACO3

Note:

• = BICARBONATE AS CACO3 = BICARBONATE • 1.22

Unit Inconsistencies

Any inconsistencies in units for a particular medium and test group code are converted to the appropriate consistent units (e.g., all results for dissolved metals analyses are expressed in units of µg/L). This step is performed so that data for one chemical can be combined for quantitative data-analysis tasks such as calculation of summary statistics.

Multiple Fields of Analytical Data

The main raw data table can contain data from the laboratory and from the data validation subcontractor for the same record. Validated data, if available, are placed in the OU 3 database. The following fields contain corresponding data from the two sources:

LABORATORY	DATA VALIDATORS
RESULT	VRESULT
QUALIFIER	VQUAL
UNIT	VUNIT
DETECT LIMIT	VDETECT
ERROR	--NO FIELD--

The protocols listed below are used to incorporate data from the laboratory and data validators:

- If the VRESULT field in the RFEDS data contains a result, then the value from VRESULT is placed in a new field (i.e., NEWRESULT) in the OU 3 database.

- If the VRESULT field in the RFEDS data is blank, the value in the RESULT field is placed in the NEWRESULT field in the OU 3 database.

- The UNIT, DETECT LIMIT, and ERROR fields are treated the same as the VRESULT and RESULT fields. NEW UNIT, NEW DETECT LIMIT, and NEW ERROR fields were created in the OU 3 database to contain the data selected by the protocol described above.

- The QUALIFIER and VQUAL fields from the RFEDS data are concatenated in a NEWQUALIFIER field in the OU 3 database.

The NEW RESULT, NEW UNIT, NEW DETECT LIMIT, NEW ERROR, and NEW QUALIFIER fields are used for quantitative data-analysis tasks.

Inconsistencies in the RFEDS TEST GROUP CODES

The RFEDS data contain multiple codes in the TEST GROUP CODE field for the same general group of chemicals. Two new fields were created in the OU 3 database, MAIN TEST GROUP CODE and GENERAL TEST GROUP CODE, to standardize the grouping of chemicals into main sample preparation/analytical method categories (e.g., DMETAL-CLP-NONCLP refers to dissolved metals) and general chemical categories (e.g., METALS refers to both dissolved and total metal analyses), respectively. Table A-4 summarizes codes used in the RFEDS TEST GROUP CODE field and corresponding codes in the MAIN TEST GROUP CODE and GENERAL TEST GROUP CODE fields in the OU 3 database.

TABLE A-4

RFEDS TEST GROUP CODE INCONSISTENCIES

RFEDS Test Group Code	Main Test Group Code	General Test Group Code
BNACLP	SVOA-ORG-CLP	SVOAS
CLHERB615	CL-HERB-EPA615	PESTICIDES
DMETADD	DMETAL-CLP-NONCLP	METALS
DIOX613	DIOX-PEST-EPA613	PESTICIDES
DPEST613	DIOX-PEST-EPA613	PESTICIDES
DMETCLPTAL	DMETAL-CLP-NONCLP	METALS
DMETNOCLP	DMETAL-CLP-NONCLP	METALS
DRADS	DISSOLVED-RADS	RADIONUCLIDES
DMETCLP	DMETAL-CLP-NONCLP	METALS
DSMETCLP	DMETAL-CLP-NONCLP	METALS
METADD	METAL-CLP-NONCLP	METALS
RFIN	WATER-QUALITY	WATER-QUALITY
METCLP	METAL-CLP-NONCLP	METALS
PAHCOM610	PAH-PEST-PCB-EPA610	PESTICIDES
PEST608	OCLPEST-EPA608	PESTICIDES
PESTCLP	PESTICIDE-CLP	PESTICIDES
PHPEST610	PAH-PEST-PCB-EPA610	PESTICIDES
PSTCLPTCL	PESTICIDE-CLP	PESTICIDES
PSTPCB508	PEST-PCB-EPA508	PESTICIDES
RFME	METAL-CLP-NONCLP	METALS
RFMS	DMETAL-CLP-NONCLP	METALS
RFPP	PESTICIDE-CLP	PESTICIDES
SMETCLP	METAL-CLP-NONCLP	METALS
RFRA	TOTAL-RADS	RADIONUCLIDES
SELCOM625	SVOA-ORG-CLP	SVOAS

TABLE A-4

RFEDS TEST GROUP CODE INCONSISTENCIES

RFEDS Test Group Code	Main Test Group Code	General Test Group Code
RFVO	VOA-ORG-CLP	VOAS
SELC0502.2	VOA-EPA502.2	VOAS
RFSV	SVOA-ORG-CLP	SVOAS
TRADS	TOTAL-RADS	RADIONUCLIDES
RFRS	DISSOLVED-RADS	RADIONUCLIDES
TRIPES619	TRIPEST-EPA619	TRIPESTICIDES
SMETNOCLP	METAL-CLP-NONCLP	METALS
SVOCLPTCL	SVOA-ORG-CLP	SVOAS
SMETCLPTCL	METAL-CLP-NONCLP	METALS
VOA502.2	VOA-EPA502.2	VOAS
VOACLP	VOA-ORG-CLP	VOAS
VOCCLPTCL	VOA-ORG-CLP	VOAS
WQPL	WATER-QUALITY	WATER-QUALITY
OCLPEST608	OCLPEST-EPA608	PESTICIDES

STEP 4 – Identify and resolve redundant data records.

Step 4 of the cleanup process is designed to identify and remove redundant records from the OU 3 database and also uses the script XCLEANUP.SC. Step 4 includes the following procedures:

A. The main table is broken into subsets (i.e., Radionuclides, Metals, Volatile Organic Compounds, Pesticides, and Water-Quality parameters), and the algorithm described below is performed for each subset of data. For each subset, additional tables are created (i.e., a KEEP table for records that will be retained in the OU 3 database and REJECT tables) that require further processing.

B. The records in the subset table to be processed are sorted in the following order:

1. **SAMPLE NUMBER**
2. **CHEMICAL NAME**
3. **MAIN TEST GROUP CODE**

C. As each subset table is parsed, all records having the same entries in the **SAMPLE NUMBER, CHEMICAL NAME,** and **MAIN TEST GROUP CODE** fields are copied to a temporary table. When the entries in the **SAMPLE NUMBER, CHEMICAL NAME,** and **MAIN TEST GROUP CODE** fields change, processing moves to Step 4-D, 4-F, or 4-G, depending on the type of records contained in the temporary table. When processing returns to Step 4-C, it continues with the next group of records having the same **SAMPLE NUMBER, CHEMICAL NAME, MAIN TEST GROUP CODE,** until all records have been processed.

D. If the temporary table includes one validated record, the following protocols are used:

- The records in the temporary table are placed in a REJECT table if the **NEW RESULT** field (and **ERROR** field if the Radionuclides subset table is being processed) is blank for all records.

- The validated record is placed in the KEEP table if the **NEW RESULT** field of the validated record contains a value. All nonvalidated records in the temporary table are placed in a REJECT table.

Processing returns to Step 4-C.

E. If the temporary table includes more than one validated record, the following protocols are used:

- One of the validated records is placed in the KEEP table if the validated records have identical values in the **NEW RESULT** field. All other validated and nonvalidated records are deleted.

- If the **RESULTS** field of the records in the temporary table are not identical or are blank, all records in the temporary table are placed in a REJECT table.

Processing returns to Step 4-C.

F. If the temporary table contains one nonvalidated record, the following protocols are used:

- The record is placed in the KEEP table if the **RESULT** field (and **ERROR** field if the Radionuclides subset table is being processed) is not blank.
- The record is placed in a REJECT table if the **RESULT** field is blank.

Processing returns to Step 4-C.

G. If the temporary table contains more than one nonvalidated record, the following protocols are used:

- One of the nonvalidated records is placed in the KEEP table if the values in the **RESULT** field (and **ERROR** field if the Radionuclides subset table is being processed) are identical.
- All of the records in the temporary table are placed in a REJECT table if the **RESULT** fields are not identical or blank.

Processing returns to Step 4-C.

Tables that are created by Step 4 include:

RADS.db	Radionuclide subset table
RDKEEP.db	KEEP table for the Radionuclides subset
RDREJ61.db	Radionuclides REJECT table (validated record; **RESULT** and/or **ERROR** field is blank)

RDREJ62.db Radionuclides REJECT table (one validated record kept; all corresponding nonvalidated records placed in this table)

RDREJ63.db Radionuclides REJECT table (more than one validated record; no duplicate results; all records rejected)

RDREJ64.db Radionuclides REJECT table (one nonvalidated record rejected; RESULT field blank)

RDREJ65.db Radionuclides REJECT table (more than one nonvalidated record; no duplicate results; all records rejected)

Step 4 is also followed to create corresponding tables for the Metals, Volatile Organic Compounds, Pesticides, and Water-Quality parameters.

STEP 5 – Assemble the main cleaned-up table.

In Step 5 of the cleanup process, all of the KEEP tables are assembled into one table (i.e., DT{date}.db.; {date} indicates the date when the table was assembled or updated).

STEP 6 – Produce potential problem records report.

Hardcopy reports of the rejected records are made from the REJECT tables for each subset of data (e.g., Radionuclides, Metals, etc.). These reports are used to resolve problems with data records.

STEP 7 – Resolve problem records.

EG&G data-management staff review data-problem reports and resolve the problem or redundant records. The following list summarizes the resolution of the types of data problems found after importing RFEDS data extractions on February 16, 1994:

- Blank **RESULT** field for Cesium-137: These records were nondetects and the value presented in the **DETECTION LIMIT** field should also be used in the **RESULT** field.

- Blank **ERROR** field for Plutonium-239/240: EG&G provided value.

- Redundant nonvalidated records for Total Organic Carbon analysis: EG&G provided RFEDS ID number of the records to be retained in the OU 3 database; other records for the same sample number were deleted.

- Nonvalidated results for surface soil samples: EG&G used nonvalidated records; validation could take from 1 to 6 months.

The following protocols are used for redundant validated records:

- If analysis dates are different for redundant records, the record with the most recent date is selected for the OU 3 database.

- If the analysis dates are the same for redundant records, selection of the record to be used in the OU 3 database is based on the Reason Codes associated with the Validation Codes.

STEP 8 – Create final database tables.

Corrected problem records and records selected from a group of redundant records for use in the OU 3 database are added to the DT{date}.db table.

STEP 9 – Copy main table to the OU 3 database directory for RFETS.

The updated DT{date}.db table is copied to the OU 3 database directory for RFETS.

STEP 10 – Notify persons using OU 3 database of updated main table.

Persons using OU 3 data are notified of the new table with a DATABASE UPDATE form.

Steps 3 through 10 are repeated with a modified cleanup script using QC data that were separated from original sample data during the cleanup process. The DQ{date}.db table is then created using cleaned-up QC data.

A-4.0 ADDITIONAL DATA INPUT

Additional data were entered into the OU 3 database to supplement the data extracted from RFEDS, including data from the following sources:

- 1984/85 Sediment Sampling Investigation (DOE, 1991) (see Attachments 1 and 2 for a discussion of analyses performed to determine the useability of these data in the RFI/RI report for OU 3).
- Rock Creek Background Soil Samples (DOE, 1993a).
- Jefferson County Sampling Area Soil Samples.
- Background Geochemical Characterization Report (DOE, 1993b).
- Benchmark – Survey Data for Points and Polygons.

These additional data were received in various formats, and different procedures were used to prepare the data for use in the OU 3 database, depending on the source. Table A-5 summarizes the dates received, format, and types of data and data preparation procedures for each of these sources.

Table A-5
Additional Data Sources

Source Name	Format	Description	Preparation Procedures
1983/84 Sediment Sampling Investigations Data (DOE, 1991)	Hardcopy data	1984 sediment data for IHSS 200 and IHSS 201	1. Enter data into Paradox 2. Perform 100% QC check of Paradox data against hardcopy data 3. Create table of data (SL{date}.db)
Rock Creek Background Soil Data (DOE, 1993a)	Hardcopy tables	Background surface soil data for 18 locations; radionuclides	1. Enter data into Excel 2. Perform 100% QC check of Excel output against hardcopy data 3. Import data to Paradox 4. Create Paradox tables for data users (OT{date}.db-original samples, OQ{data}.db-QC samples, and O1{date}.db-all samples

Table A-5
Additional Data Sources

Source Name	Format	Description	Preparation Procedures
Jefferson County Sampling Area Soil Data (extracted from RFEDS)	ASCII file (Column-delimited)	Surface soil sampling results for 47 sample locations; Am-241 and Pu-239/240	1. Convert data to comma-separated/ alpha field-delimited files 2. Import files to Paradox 3. Run data through preprocessing and cleanup scripts 4. Create Paradox tables for data users (JT{date}.db-original samples , JQ{date}.db-QC samples, and JS{date{.db)-all samples)
Background Geochemical Characterization Report Data (DOE, 1993b)	ASCII files (Column-delimited)	Background data for stream surface water, stream sediments, and groundwater	1. Convert data to comma-separated/ alpha field-delimited files 2. Import files to Paradox 3. Remove seep locations, correct inconsistent units/chemical names 4. Create Paradox table (NB{date}.db)

Table A-5
Additional Data Sources

Source Name	Format	Description	Preparation Procedures
Benchmark Survey Data	ASCII files (Comma-separated)	Survey coordinates for sample points and polygons (surface soil plots)	1. Import data into Paradox 2. Convert coordinates to state plane coordinates 3. Create table for points (BP{date}.db) 4. Create table for polygons (BY{date}.db)

A-5.0 DATA ANALYSIS TABLE

The Data Analysis table (DA{date}.db) is composed of records from the DT{date}.db, JT{date}.db, OT{date}.db, and NB{date}.db tables. Additionally, the DA{date}.db table contains fields that reflect application of data-evaluation protocols. This section describes the data-evaluation protocols and outlines the procedures used to prepare the DA{date}.db table.

A-5.1 Data Evaluation Protocols

The data-evaluation protocols for the Draft RFI/RI report are based on Guidance for Data Useability in Risk Assessments (EPA, 1990) and a guidance memorandum from EG&G (EG&G, 1994, included as Attachment 3). The eleven protocols described in this section are the data manipulation rules that were applied to prepare the DA{date}.db table for quantitative data analysis tasks. The protocols were designed to identify and eliminate data considered unacceptable for quantitative data analysis (e.g., data rejected as a result of data validation). Additionally, the protocols provide for consistent treatment of nondetects, QC samples, and other specific categories of data in the quantitative data analyses.

A-5.1.1 Nonvalidated Data

Any nonvalidated data in the OU 3 database were included in the DA{date}.db table and were used for quantitative data-analysis tasks for the Draft RFI/RI report. A total of 1,082 records in the OU 3 database used for the COC selection process (7 percent) were nonvalidated.

A-5.1.2 Validated/Qualified Data

All data qualified with a "J," and any other qualifiers except those with an "R," in the **VALIDATION** or **NEWQUALIFIER** fields were included in the DA{date}.db table and were used in the quantitative data analysis tasks for the Draft RFI/RI report. Validated data flagged with an "R" in the **VALIDATION** field or nonvalidated data flagged with an "R" in the **NEWQUALIFIER** field were not included in the DA{date}.db table and therefore were not used in any

quantitative data analyses tasks for the Draft RFI/RI report. Data flagged with an "R" are rejected because they did not meet performance requirements in the sample or in the associated QC samples. The R-qualified data may be used qualitatively in the RFI/RI report, if appropriate.

A-5.1.3 QC Samples

All QC samples (e.g., trip blanks, field duplicates, laboratory replicates, etc.) were removed from the DA{date}.db table and were not used for quantitative analysis tasks for the RFI/RI report. The QC data were used to evaluate precision, accuracy, representativeness, comparability, and completeness (PARCC) under the RFI/RI Task 4.

A-5.1.4 Treatment of Detects/Nondetects for Inorganic Parameters

Analytical results for metals and water-quality parameters were treated as detects if the following conditions applied:

- The NEWQUALIFIER field is blank.
- A sample is not qualified with a "U" in the NEWQUALIFIER field. A sample qualified with a "U" is a nondetect and is below the instrument detection limit.
- A sample is qualified with a "B" in the NEWQUALIFIER field. The "B" qualifier signifies that the analytical result was below the contract-required reporting limit (CRDL) but above the instrument detection limit (IDL). B-qualified data are considered to be detects and are used as such.

A-5.1.5 Treatment of Nondetects – Volatiles, Semivolatiles, Pesticides, and PCBs

When applying any parametric analytical test, one-half the reported analytical result (the **NEWRESULT** field in the database) was used for organic samples flagged with a "U" in the **NEWQUALIFIER** field. All data flagged with a "U" were counted as nondetects when performing detection frequency calculations.

When applying any nonparametric analytical test, the reported analytical result (the **NEWRESULT** field in the database) was used for organic samples flagged with a "U" in the **NEWQUALIFIERS** field.

A-5.1.6 Treatment of Nondetects – Radionuclides

DOE Order 5400.xy provides guidance on the treatment of radionuclide results at or below the detection limit. The DOE order states: "All of the actual values, including those that are negative, *should* be included in the statistical analyses. Practices such as assigning a zero, the detect limit value, or some in-between value to the below-detectable data point, or discarding those data points can severely bias the resulting parameter estimates and *should* be avoided. ... Data from censored distributions are more amenable to standard statistical analyses than are those from truncated distributions ...."

Based on the DOE guidance, all radionuclide results were treated as detects for quantitative data-analysis tasks except for calculation of detection frequency. For calculating detection frequency, all results flagged with a "U" in the NEWQUALIFIER field were counted as nondetects.

A-5.1.7 Treatment of Negative and Zero Results for Radionuclides

Based on DOE Order 5400.xy, all radionuclides results, including negative and zero values, were used in quantitative data-analysis tasks. For statistical tests requiring log-transformations of the radionuclide results (e.g., background statistical comparison tests), the distributions of

results for a particular analyte for both OU 3 data and background data were shifted by adding a constant value to each result so that all results were positive. This shift was performed because calculation of the natural log of zero or negative values results in an error. Therefore, negative and zero values could not be included in the comparison test when log-transformation was required if the shift was not performed.

A-5.1.8 Treatment of Error

The impact of the ERROR reported for the radionuclide parameters will be discussed in the RFI/RI Uncertainty Section. In cases where the ERROR is equal to or greater than 0.5 times the **NEWRESULT** value, there is less confidence in the reported result and a higher degree of uncertainty.. For example, if the error is subtracted from the result, the reported value may be less than the detection limit. Data that fall in this category will be identified but not altered for quantitative data-analysis tasks.

A-5.1.9 Treatment of Outliers

An outlier is an extreme observation that does not conform to the pattern established by other observations and is unlikely to be a valid member of the population of interest. An outlier may be the result of an incorrectly read, recorded, or transcribed measurement; an incorrect calculation; an error in documentation (field or laboratory); or an actual environmental condition. To evaluate the presence of outliers, the following procedure was applied to the analytes, by sample type, for the sediment, surface-water, and groundwater background data in the Background Geochemical Characterization Report (DOE, 1993b) only (this screening process was not applied to OU 3 data):

1. Anomalous data were flagged.

2. These flagged values were examined, then checked individually if judged to be geochemically questionable. Each flagged outlier was evaluated with respect to the historical trend of the data for that specific location, as well as laboratory

conditions such as matrix interference, in an attempt to determine why the datum was aberrant.

3. If the outlier resulted in a correctable error, the value was changed, and the correct value was included in the data set. Data that were believed to have resulted from laboratory contamination (e.g., acetone "hits"), irresolvable transcription errors, or other noncorrectable errors that gave results not thought to be representative of background were excluded from subsequent statistical analyses.

Outliers listed in Appendix E of the Background Geochemical Characterization Report have been excluded from the DA{date}.db table of the OU 3 database and therefore, were not used in statistical comparison tests.

A-5.1.10 Averaging of Analytical Results for Surface Soil Samples Collected Using Different Methods

Surface-soil samples were collected by two different methods: the Colorado Department of Public Health and the Environment (CDPHE) method and the RFETS/Modified Hazel method (MHM). The paired t-test at the 95 percent confidence level showed that the results from these two methods were not significantly different (see Attachment 4 for a detailed discussion of the statistical analysis). Therefore, results of the two methods for a sample location were averaged and this mean value for the sample location was entered into the DA{date}.db table of the OU 3 database in the NEWRESULT field for use in quantitative data-analysis tasks.

A-5.2 PREPARATION OF DATA-ANALYSIS TABLES

The following procedures were used to prepare the DA{date}.db table:

1. A copy of the DT{date}.db table was made and named DT2DA.db.

2. The "Rejected" (**VALIDATION** field contains an "R") data records were removed from the DT2DA.db table.

3. The units were checked for consistency.

4. The codes in the **CHEMICAL NAME** field were checked for consistency.

5. A **DETECT** field was added to the table. The **DETECT** field indicates if a record is a nondetect (U) or a detect ([BLANK]). If the **NEW QUALIFIER** field contained a "U," then the **DETECT** field for the corresponding record contains a "U;" otherwise, the **DETECT** field was left blank.

6. An **AREA** field was added to the table. The **AREA** field denotes if the record is background (B) or OU 3 site (S) data. For the DT2DA.db table, the **AREA** field was set to "S" to denote that it is OU 3 site data.

7. The data from the DT2DA.db table were inserted into the DA{date}.db table.

Procedures 1 through 7 were repeated for the JT{date}.db, OT{date}.db, and NB{date}.db tables. After all tables were combined into the DA{date}.db table, the following procedures were performed:

8. The DA{date}.db table was checked for overall consistency of units.

9. The DA{date}.db table was checked for overall consistency of codes in the **CHEMICAL NAME** field.

10. Fields from the data grouping table (DG{date}.db) were added to the DA{date}.db table. Using the **LOCATION CODE** field as a link from the DA{date}.db to the DG{date}.db, the **IHSS, DGTYPE, DGGRABCORE,** and **DGSOIL** were linked into the DA{date}.db table.

11. New fields (i.e., ADJ DETECT and ADJ RESULT), based on the data-evaluation protocols, were set up in the DA{date}.db table. The values in the DETECT and NEW RESULT fields were copied into the ADJ DETECT and ADJ RESULT fields so that both sets of fields contained the same data. The ADJ fields were then adjusted to reflect application of the data evaluation protocols, and the original fields were not changed.

12. For all radionuclide records, the ADJ DETECT field was set to a [BLANK] value to denote the record as a detect value.

13. For all metal records, if the NEW QUALIFIER field contained a "B," then the ADJ DETECT field value was set to a [BLANK] value to denote the record as a detect.

14. For all records that contained a "U" in the ADJ DETECT field after completing procedures 12 and 13, the value in the ADJ RESULTS field was replaced with a proxy value (i.e., one-half of the value in the NEW RESULT field).

15. The updated DA{date}.db table was copied to a separate directory.

16. Persons using OU 3 data were notified of the updated DA{date}.db table with a DATABASE UPDATE form.

A-6.0 QUALITY CONTROL CHECKS

The following QC checks were performed to verify the completeness and consistency of the OU 3 database:

- A QC audit of the ST{date}.db table was performed using printouts of the original source data. Any error or inconsistencies found in the ST{date}.db table were corrected.

- A list of missing data (i.e., data requested from the laboratories but not contained in the DT{date}.db or DQ{date}.db tables) was produced by comparing the ST{date}.db table (i.e., sample tracking matrix that contains all requested analyses for each sample number) to the DT{date}.db and the DQ{date}.db tables. The records listed on the missing data list were checked against the RFEDS data received from EG&G to verify that all data received from RFEDS were imported into the OU 3 database.

- SAMPLE LOCATION codes in the DB{date}.db, DG{date}.db, and DA{date}.db tables for OU 3 field investigation data were compared to SAMPLE LOCATION codes in the ST{date}.db table. No inconsistencies were found between SAMPLE LOCATION codes in the tables.

- The DA{date}.db and DB{date}.db tables were checked for consistency of analytical result units for each CHEMICAL NAME. Records with inconsistent units were corrected.

- The DA{date}.db table was queried to verify it did not contain any QC samples or R-validated/qualified data. No QC samples or R-validated/qualified data were found.

- The DA{date}.db table was queried to verify it contained data for the following SAMPLE TYPES only: SS-surface soil plots, PT-pit trench soil samples, SW-surface water, SD-sediment, GW-groundwater, and BI-biota. These SAMPLE TYPES were found along with several records with "UN" (unknown) in the SAMPLE TYPE field. The records with "UN" were corrected.

- Sample locations contained in the DG{date}.db table for each medium were checked against the GIS plots to verify all sample-location data were transferred to ARC/INFO. Sample locations were found to be consistent between the DG{date}.db table and the GIS plots.

- Ten percent of the analytical data displayed on the GIS plots was checked against the NEW RESULT field in the DA{date}.db table for corresponding sample locations to verify that the analytical data were accurately transferred to ARC/INFO. No errors were found in the analytical data on the GIS plots.

Additionally, a QC check of the cleanup script was performed using a sample data set that contained historical data, QC data, and redundant records. No errors were found in the data set after cleanup; historical records and QC data were separated, and redundant records were placed into the appropriate REJECT tables, as described in Subsection A-3.0.

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APPENDIX B

GUIDE FOR CONDUCTING STATISTICAL COMPARISONS OF RFI/RI DATA AND BACKGROUND DATA AT THE ROCKY FLATS PLANT

APPENDIX B
BACKGROUND COMPARISON FOR METALS AND RADIONUCLIDES

Concentrations of metals and activities of radionuclides measured in surface soil, subsurface soil, and groundwater can be compared to RFETS background concentrations in order to identify OU analytes whose concentrations are statistically higher than background levels. These analytes are then identified as potential chemicals of concern for further evaluation. The RFETS background data for subsurface soil and groundwater were reported in the Background Geochemical Characterization Report (DOE 1993). The background surface soil data were collected in the Rock Creek Area during the 1991 OU1 Phase III investigation and the 1993 OU2 Phase II investigation. Analytical results from each medium can be pooled, and the background comparison performed on an OU-wide basis. OU UHSU groundwater results can be compared to background data for the UHSU. OU borehole results can be compared to background data from UHSU geologic material. OU surface soil results can be compared to data collected in the Rock Creek area.

The procedures applied in the background comparison are shown in the flow chart in Figure B-1. Three major steps are involved: (1) data aggregation, (2) statistical background comparisons, and (3) lognormal UTL assessment. Each of these steps is discussed below.

B.1 DATA AGGREGATION

The chemical data are grouped by medium into three categories: (1) surface soil, (2) subsurface soil above the water table, and (3) groundwater (UHSU). Analysis are performed on both unfiltered and filtered groundwater samples. An example of a background comparison summary table is provided in Table B-1.

B.2 STATISTICAL BACKGROUND COMPARISON

Background comparisons are performed according to the procedures given in the "Guidance Document, Statistical Comparisons of Site-to-Background Data in Support of RFI/RI Investigations" (EG&G 1994), which was primarily based on the methodology proposed by Gilbert (Gilbert 1993). The formal statistical tests are the Gehan test, Slippage test, Quantile test,

and t-test. Analytical results are also compared to the upper tolerance limit ($UTL_{99/99}$) of background to identify high concentrations that may represent localized areas of contamination within the OU. The conditions for applying each of the tests are briefly discussed below.

B.2.1 Formal Statistical Tests

Four formal statistical test are performed to test the difference between the background and site populations. If any of the four statistical test are significant, the analyte is considered to be a potential chemical of concern. Significance is defined as a p-value less than or equal to 0.05, the Type I (false positive) error rate. Non-detects of metals are treated as described below for each test. All the radionuclide results are treated as detects (per DOE Order 5400).

Gehan Test

The Gehan test (Gehan 1965, explained in Gilbert 1993) is non-parametric ranking test. It is performed for all analytes. For non-detects, the reporting limits are used for ranking purposes.

Slippage Test

The slippage test (Rosenbaum 1954), a non-parametric test, is performed by comparing the OU measurements to the maximum background measurement (detect or non-detect). The p-value for the probability of the number of site measurements greater than the maximum background measurement is calculated. Reporting limits are used for non-detects.

Quantile Test

The Quantile test (Gilbert and Simpson 1992), a non-parametric test, is performed by first ranking the combined background and OU measurements from largest to smallest. If there are no non-detects among the top 20 percent of the combined background and OU measurements, the probability of the number of site measurements within the top 20% of the data set is calculated. If there are any non-detects among the top 20% of the measurements, no Quantile test is performed.

t-Test

The t-test, a parametric statistical test, is performed if these conditions are met: (1) the non-detects in each of the data sets is less than 20 percent of the measurements; and (2) EITHER each of the data sets contains at least 20 points, OR both of the data sets are normally distributed.

For simplicity, the t-test is only performed when condition (1) and the first option of condition (2) are met. Non-detect results for metals are replaced by one-half the reporting limits.

The homogeneity of the variance is tested following Levene's test (EPA 1992). If the variances from both data sets are the same, the standard t-test is performed. If the variances are not the same, the unequal variance t-test (Helsel and Hirsch 1992) is performed.

B.2.2 Upper Tolerance Limit ($UTL_{99/99}$) Comparison

For each analyte in the background data, an upper tolerance limit with 99 percent confidence and 99 percent coverage ($UTL_{99/99}$) is calculated, assuming the background data are normally distributed (EG&G 1994). In calculating the UTL, if non-detects were less than 80 percent of the data, one-half the reporting limit is used as the result for non-detect samples. Otherwise, the maximum background measurement, instead of the $UTL_{99/99}$, is used in the comparisons. For the radionuclides, all results are treated as detects (EG&G 1994).

Each of the OU measurements are compared to the applicable $UTL_{99/99}$. If one or more OU measurement exceeds the background $UTL_{99/99}$, the analyte is considered as a potential chemical of concern for further evaluation, even if the analyte did not exceed background levels according to the formal statistical evaluation.

B.3 BACKGROUND COMPARISON RESULTS

The number of inorganic potential chemicals of concern resulting from the background comparisons can be summarized as shown in Table B-1.

B.4 LOGNORMAL UTL ASSESSMENT

Analytes that are below background according to the formal statistical tests but fail the $UTL_{99/99}$ comparisons are evaluated further. The evaluation consists of performing a lognormal $UTL_{99/99}$ comparison if the background data were lognormally distributed.

According to the background comparison methodology (EG&G 1994), the $UTL_{99/99}$ is calculated assuming a normal distribution of background data. However, a lognormal distribution may better describe some geochemical data (EPA 1992), in which case calculating a lognormal UTL is more appropriate, as indicated in Gilbert (1993). Lognormal-based $UTLs_{99/99}$ are calculated for analytes that pass the formal statistical tests but fail the normal-based $UTL_{99/99}$ comparison. If an analyte passes the lognormal-based $UTL_{99/99}$ comparison, probability plots are generated for both normal and lognormal distributions. If the probability plots indicate that the data better fits a lognormal distribution, and the analytical results are less than the lognormal $UTL_{99/99}$, then the analyte is eliminated from the potential chemical of concern list.

A positive constant can be added to the radionuclide results (including negative and zero values) to make all the results positive prior to log transformations. After the lognormal $UTL_{99/99}$ is calculated based on this shifted distribution, the constant is subtracted from the calculated $UTL_{99/99}$ to get the "true" lognormal $UTL_{99/99}$ value.

The results of the lognormal based $UTL_{99/99}$ comparisons can then be presented in remarks columns in summary tables. Based on the results of the lognormal $UTL_{99/99}$ comparison, analytes are eliminated as potential chemicals of concern:

Figure B-1 Background Comparison Process

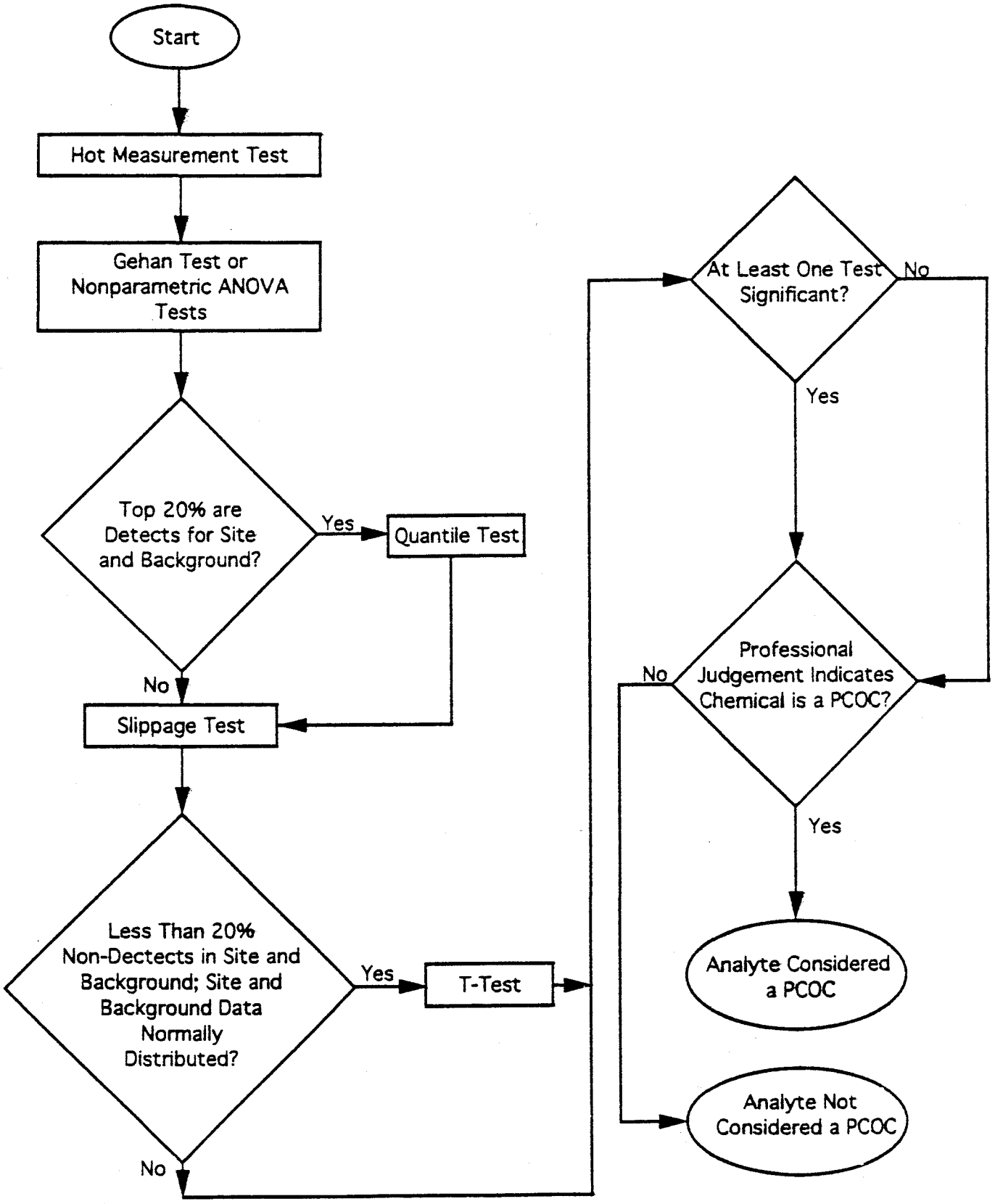

TABLE B-1
EXAMPLE BACKGROUND COMPARISON SUMMARY

Media	Background Data[a]	OU Data[a]	Chemical Group[a]	No. of Analytes in Comparison[b]	No. of Analytes Significant in Tests[b]	No. of Analytes Greater than $UTL_{99/95}$[b]	No. of PCOC[b]
Subsurface Soil	UHSU Subsurface Soil	Subsurface Soil Above Groundwater Table	Metals Radionuclides				
Surface Soil	Rock Creek Surface Soil	Surface Soil	Metals Radionuclides				
Groundwater	UHSU Groundwater	UHSU Groundwater	Unfiltered Metals Filtered Metals Unfiltered Radionuclides Filtered Radionuclides				

a. The information provided in this table is shown as an example only
b. Values have not been shown in these columns because the table is an example only

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